



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C., 20460

**MEMORANDUM****Date: 11/16/11**

**SUBJECT:** Response to Public Comments on the Fipronil Registration Review  
Problem Formulation (PC Code 129121 DP394079)

**FROM:** Stephen Wentz, Ph.D., Biologist  
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**THROUGH:** Nancy Andrews, Branch Chief  
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**TO:** Susan Bartow, Chemical Review Manager  
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Pesticide Re-evaluation Division  
Office of Pesticide Programs (7505P)

The Environmental Fate and Effects Division (EFED) has reviewed and prepared the following responses to issues and comments received by the Agency concerning the Registration Review – Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered Species, and Drinking Water Assessments for Fipronil (PC Code 129121; DP 387319). Comments and/or studies were received from the California Stormwater Quality Association (CASQA), Department of Water Resources (County of Sacramento, CA), CA Regional Water Quality Control Board, SF Bay Region and Central Valley Region, ToXcel LLC, Tri-TAC (a technical advisory group for Publicly Owned Treatment Works), Bayer CropScience, and BASF Corporation. Comments and the Agency's responses to comments are organized by common theme:



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## General Comments on Fipronil

### *Bringing relevant studies to the attention of the Agency*

The Agency greatly appreciates receiving relevant scientific studies. The agency typically has access to a vast array of toxicology data through the Ecotoxicology (ECOTOX) database maintained by the Agency, but does not have ready access to environmental fate studies and pesticide usage and monitoring data summarized in proprietary or state and local agency reports/databases. The following studies were submitted to the agency through the docket:

- SM Bay, DJ Greenstein, KA Maruya, W Lao. December 2010. *Toxicity Identification Evaluation of Sediment (Sediment TIE) in Ballona Creek Estuary: Final Report*. Technical Report 634. Southern California Coastal Water Research Project. Costa Mesa, CA.
- Ensminger, M. and K. Kelley. July 2011. Monitoring Urban Pesticide Runoff in Northern California, 2009 – 2010. California Environmental Protection Agency, Department of Pesticide Regulation, Environmental Monitoring Branch, Surface Water Protection Program. Report 264. pp. 31.
- Hintzen, E.P., M.J. Lydy and J.B. Belden. 2009. Occurrence and potential toxicity of pyrethroids and other insecticides in bed sediments of urban streams in central Texas. *Environmental Pollution*. 157: 110-116.
- Jiang, W., Lin, K., Haver, D., Qin, S., Ayre, G., Spurlock, F. and Gan, J. (2010), Wash-off potential of urban use insecticides on concrete surfaces. *Environmental Toxicology and Chemistry*, 29: 1203–1208.
- Lao, W., Tsukada, D., Greenstein, D. J., Bay, S. M. and Maruya, K. A. (2010), Analysis, occurrence, and toxic potential of pyrethroids, and fipronil in sediments from an urban estuary. *Environmental Toxicology and Chemistry*, 29: 843–851.
- Lin, K., Haver, D., Oki, L. and Gan, J. (2009), Persistence and sorption of fipronil degradates in urban stream sediments. *Environmental Toxicology and Chemistry*, 28: 1462–1468.
- Maul, J. D., Brennan, A. A., Harwood, A. D. and Lydy, M. J. (2008), Effect of sediment-associated pyrethroids, fipronil, and metabolites on *Chironomus tentans* growth rate, body mass, condition index, immobilization, and survival. *Environmental Toxicology and Chemistry*, 27: 2582–2590.
- TDC Environmental. June 2010. Pesticides in Urban Runoff, Wastewater, and Surface Water: Annual Urban Pesticide Use Data Report 2010. Pp. 41.  
([http://www.up3project.org/documents/UP3Use2010\\_Final.pdf](http://www.up3project.org/documents/UP3Use2010_Final.pdf))

**Comment:** Please utilize the substantial information available in the scientific literature to inform the environmental risk assessment. While we support the plan to use information from U.S. EPA’s agency-wide ECOTOX database, we recommend that U.S. EPA also do literature searches and keep an eye out for upcoming publications because a great deal of scientific work related to fipronil is currently underway—including environmental transport and monitoring studies that would not be captured in the ECOTOX database. (California Stormwater Quality Association, p. 10)

**EPA Response:** The Agency will try to base the fipronil registration review assessment on the latest information available at the time the assessment is prepared. The Agency appreciates the information received from the public, other governmental agencies, and non-governmental organizations.

*Comments Indicating that Fipronil Concentrations are High in Urban Streams*

**Comment:** Although fipronil is a relatively new insecticide that is more heavily used in urban areas than in agriculture, it has already been detected in watersheds across the U.S.<sup>1</sup> U.S. Geological Survey National Water-Quality Assessment monitoring found a significant upward trend in fipronil concentrations in the nation's waterways between 2000 and 2008.<sup>2</sup> In recent years, fipronil and its degradates have been found in urban runoff,<sup>3</sup> urban creeks and rivers,<sup>4</sup> sediments in urban watersheds,<sup>5</sup> and estuarine sediments.<sup>6</sup> We have enclosed a brief summary of monitoring data we identified in a short literature search. This summary shows:

- Numerous water samples from highly urbanized watersheds had fipronil concentrations above U.S. EPA OPP aquatic life benchmarks.<sup>7</sup>
- Many sediment samples from highly urbanized watersheds contained fipronil and its degradates at concentrations that may be harmful to sediment-dwelling organisms.<sup>8</sup> (California Stormwater Quality Association, p. 3)

**Comment:** Although fipronil is a relatively new insecticide with relatively low usage in California (<30,000 pounds active ingredient annually as of 2008<sup>9</sup>), it was commonly

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<sup>1</sup> Sprague, L. A. and L. H. Nowell (2008). "Comparison of Pesticide Concentrations in Streams at Low Flow in Six Metropolitan Areas of the United States." *Environmental Toxicology and Chemistry* 27(2): 288-298; see also data from the USGS NACWA data warehouse (<http://infotrek.er.usgs.gov/apex/f?p=NAWQA:HOME:0>).

<sup>2</sup> Ryberg, K.R., Vecchia, A.V., Martin, J.D., and Gilliom, R.J. (2010). Trends in pesticide concentrations in urban streams in the United States, 1992–2008: U.S. Geological Survey Scientific Investigations Report 2010–5139, 101 p.

<sup>3</sup> Bondarenko, S., Oki, L., Haver, D., Li, J.X., Gan, J. (2011) "Fipronil and Its Biologically Active Derivatives in Urban Residential Runoff." In preparation

<sup>4</sup> Delgado-Moreno, L., K. Lin, et al. (2011). "Occurrence and toxicity of three classes of insecticides in water and sediment in two Southern California Coastal watersheds." *Journal of Agricultural and Food Chemistry*. In press; data from the USGS NACWA data warehouse

(<http://infotrek.er.usgs.gov/apex/f?p=NAWQA:HOME:0>); Ensminger, M., and R. Budd (2011). "Fipronil and Degradates Detections in Surface Waters in Urban Areas, California 2008-11." Unpublished data collected by the California Department of Pesticide Regulation. August 4.

<sup>5</sup> Hintzen, E. P., M. J. Lydy, et al. (2009). "Occurrence and potential toxicity of pyrethroids and other insecticides in bed sediments of urban streams in central Texas." *Environmental Pollution* 157(1): 110-116.

<sup>6</sup> Bay, S., D. J. Greenstein, et al. (2010). Toxicity Identification Evaluation of Sediment (Sediment TIE) in Ballona Creek Estuary: Final Report. Technical Report 634. Costa Mesa, CA: Southern California Coastal Water Research Project.

[ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/TechnicalReports/634\\_BallonaTIE.pdf](ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/TechnicalReports/634_BallonaTIE.pdf)

<sup>7</sup> [http://www.epa.gov/oppefed1/ecorisk\\_ders/aquatic\\_life\\_benchmark.htm#benchmarks](http://www.epa.gov/oppefed1/ecorisk_ders/aquatic_life_benchmark.htm#benchmarks)

<sup>8</sup> Maul, J. D., A. A. Brennan, et al. (2008). "Effect of Sediment-Associated Pyrethroids, Fipronil, and Metabolites on Chironomus Tentans Growth Rate, Body Mass, Condition Index, Immobilization, and Survival." *Environmental Toxicology and Chemistry* 27(12): 2582-2590.

detected in surface waters in recent monitoring studies conducted by the California Department of Pesticide Regulation.<sup>3</sup> Water quality monitoring data from across the country that demonstrate that:

- Numerous water samples from highly urbanized watersheds had fipronil concentrations above U.S. EPA OPP aquatic life benchmarks.<sup>7</sup>
- Many sediment samples from highly urbanized watersheds contained fipronil and its degradates at concentrations that may be harmful to sediment-dwelling organisms.<sup>8</sup> (California Regional Water Quality Control Board, San Francisco Bay Region, p. 2)

**EPA Response:** The Agency will incorporate this information into the risk assessment in accordance with the support provided in the supporting references.

#### *Comments Concerning Fipronil Use Trends*

**Comment:** In the next few years, fipronil use is expected to increase in response to coming restrictions on outdoor pyrethroid use, availability of less costly generic fipronil products, and structural pest control industry preferences. Rapid U.S. EPA action is needed to prevent another nationwide water pollution problem. (California Stormwater Quality Association, p. 4)

**Comment:** In the San Francisco Bay area, we have continued to find that pesticides used in accordance with label directions are causing toxicity in our urban water bodies. For example, Kirker Creek recently was listed under Clean Water Act §303(d) as impaired by pyrethroids.<sup>10</sup> We are very concerned that fipronil will become a significant new source of aquatic toxicity in urban creeks, because fipronil is highly toxic and can be persistent, its degradates are toxic and persistent, and its use is increasing. (California Regional Water Quality Control Board, San Francisco Bay Region, p. 1)

**Comment:** Fipronil usage is likely to increase in response to coming restrictions on outdoor pyrethroid use, availability of less costly generic fipronil products, and structural pest control industry preferences. We urge EPA to take the actions needed to prevent another widespread pesticide-related aquatic toxicity problem. (California Regional Water Quality Control Board, San Francisco Bay Region, p. 2)

**EPA Response:** The Environmental Fate and Effects Division (EFED) defers to the Biological and Economic Analysis Division (BEAD), Pesticide Re-evaluation Division (PRD), and/or Registration Division (RD) on this point.

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<sup>9</sup> TDC Environmental, Inc. (2010). "Pesticides in Urban Runoff, Wastewater and Surface Water – Annual Pesticide Use Data Report 2010." Prepared for the San Francisco Estuary Project. June 28.

<sup>10</sup> See Table 4 in the Staff Report on Evaluation of Water Quality Conditions for the San Francisco Bay Region, "Proposed Revisions to Section 303(d) List." February 2009. Available at: [http://www.waterboards.ca.gov/sanfranciscobay/board\\_decisions/adopted\\_orders/2009/R2-2009-0008.pdf](http://www.waterboards.ca.gov/sanfranciscobay/board_decisions/adopted_orders/2009/R2-2009-0008.pdf)

*Comments Suggesting Structural Pest Control Applications of Fipronil and Fipronil Concentrations in Ambient Waters are linked*

**Comment:** According to California's pesticide use reporting system, nearly all fipronil applied by professional applicators is for structural pest control.<sup>11</sup> In California, where fipronil has no approved agricultural applications, reported fipronil use approximately equals reported fipronil sales, suggesting that most fipronil is used by professionals and that the over-the-counter market is relatively small.<sup>12</sup>

There are 50 fipronil products with active registrations with both U.S. EPA and the state of California—but only one, a professional structural pest control liquid concentrate product, has significant potential to release fipronil into urban runoff. (California Stormwater Quality Association, p. 4)

**Comment:** Since the 1990's the County and other MS4 permit holders throughout California have consistently observed toxicity in runoff and receiving waters that is most likely caused by legal applications of currently registered insecticides. The problem was initially caused by chlorpyrifos and diazinon, and once those pesticides were removed from the urban market, the toxicity problem shifted to pyrethroids. The use pattern that contributed most to the observed toxicity was structural pest control applications made as a perimeter barrier around the exterior of commercial and residential buildings, with Argentine ants as the most important target organism. (County of Sacramento, p. 1)

**EPA Response:** The Agency will incorporate this information into the risk assessment in accordance with the support provided in the supporting references. The Environmental Fate and Effects Division (EFED) defers to the Biological and Economic Analysis Division (BEAD) on the interpretation of the California Pesticide Use Reporting (PUR) data.

*Cost of Regulatory Requirements under CWA if Fipronil causes Water Quality Impairments vs. Prevention under FIFRA*

**Comment:** Pesticide-related pollution in surface waters receiving urban runoff has created a multi-million dollar regulatory burden for our municipality members. When this water pollution occurs, municipalities may be subject to enforcement under National Pollutant Discharge Elimination System (NPDES) permits. Municipalities also face negative publicity and the increasing threat of litigation under the citizen suit provisions of the Clean Water Act.<sup>13</sup> There is no practical and cost-effective technology that can reduce pesticides in stormwater runoff to meet regulatory requirements. The only

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<sup>11</sup> California Department of Pesticide Regulation (DPR) (2010). Summary of Pesticide Use Report Data 2009, Indexed by Chemical, December.

<sup>12</sup> California Department of Pesticide Regulation (DPR) (2010). Summary of Pesticide Use Report Data 2009, Indexed by Chemical, December. California Department of Pesticide Regulation (DPR) (2011). "State of California Pesticides Sold in California for Year: 2009, Combined Disclosed Active Ingredients by Chemical Name." February 15.

<sup>13</sup> Natural Resources Defense Council, Inc. v. County of Los Angeles (Filed July 13, 2011) Case No. 10-56017.

technically and economically feasible way for municipalities to comply with Clean Water Act requirements is for U.S. EPA to use its pesticide regulatory authorities to prevent water pollution in urban watersheds....

Compared to the staggering public costs to respond to water pollution problems, the U.S. EPA and industry costs associated with characterizing pesticide products, assessing environmental risks, and implementing necessary mitigation measures are relatively small. (California Stormwater Quality Association, p. 2 and 3)

**Comment:** It is essential that EPA obtain the data necessary to completely review fipronil's impacts on water quality. We attest that the costs of obtaining these data upfront are dwarfed by the potential costs associated with sediment toxicity in waters of the United States, costs which include water quality monitoring; impairment analyses as required by Clean Water Act §303(d); development of Total Maximum Daily Loads to address the impairment; and associated mitigation actions. (California Regional Water Quality Control Board, San Francisco Bay Region, p. 2)

**EPA Response:** The Environmental Fate and Effects Division (EFED) defers to the Pesticide Re-evaluation Division (PRD) on these points.

#### *Pre-construction Termiticide Applications of Fipronil*

**Comment:** The Termidor label includes language (page 8) requiring that the treated area be covered with a waterproof barrier, such as polyethylene sheeting, if the foundation slab is not to be poured the same day as the treatment occurs. This existing language is similar to language that will soon be in place on most pyrethroid product labels. We encourage U.S. EPA to require that this language appear on all future fipronil product labels.

This simple practice may be sufficient to prevent post-application washing of fipronil off site should a light rain occur in the short time period before the foundation is poured; however, it might not prevent losses of fipronil into rainwater that ponds treated foundation excavations. When foundation excavations fill with water, the water is ordinarily pumped out, often into a nearby gutter that flows into the municipal storm drain system. We request that U.S. EPA examine the risks associated with pumping out water that has collected in fipronil-treated foundation areas. Estimating environmental concentrations from discharges associated with pumping events is relatively straightforward. (California Stormwater Quality Association, p. 5 and 6)

**EPA Response:** The Environmental Fate and Effects Division (EFED) defers to the Registration Division (RD) on the label language requirements. The agency will assess the pumping of water from fipronil treated excavation sites. If sample concentrations have been measured in the water collected in such excavations, the agency would appreciate receiving copies of such reports or raw data.

## *Fipronil Pet Treatments*

**Comment:** ... The Agency appears to have overlooked the fact that there are fipronil MUPs that are strictly confined to the formulation of pesticide products for use on companion animals. For some TGAI registrants, fipronil use as a spot-on product is the limit of their market niche and network.

The conceptual model of ecological risk for fipronil from pages 24 and 25 of the Agency's May 4, 2011 problem formulation memorandum<sup>14</sup> indicates that the sources of release of fipronil to aquatic habitats include spray drift, runoff, leaching to groundwater, and atmospheric transport. Sources of terrestrial exposure to fipronil include direct application to soil, spray drift, runoff, and atmospheric transport. For spot-on products containing fipronil, not one of the aforementioned exposure pathways is relevant. Thus, there are no significant or routine releases of fipronil to the environment from spot-on products.

Accordingly, we respectfully request that the Agency consider the need to separate the data requirements for fipronil use in crop, lawn, and outdoor ant control products from an appropriately reduced set of data requirements for spot-on animal care products containing fipronil. The requirement for extensive ecological testing, crop field trials, and subchronic toxicity data for "all" uses of fipronil is inappropriate for TGAI (MUPs) that are confined to use in formulating spot-on products. Such excessive data requirements may force the voluntary withdrawal of the limited-use MUPs, which would certainly be an unnecessary economic hardship for those primary registrants.

Since residential uses of fipronil lack significant exposure to the environment and are "below HED's level of concern," we request greater clarification and restriction with regard to the additional data that will likely be required on fipronil. The proposed additional ecological testing, crop field trials, and sub-chronic toxicity data identified in the registration review summary are not warranted for fipronil TGAI (MUPs) limited to the formulation of spot-on pesticide product use on companion animals. (J. Michael Kelley, Ph.D., ToXcel, p. 2 and 3)

**Comment:** In addition to the potential for human exposure, pets treated with spot-on fipronil products pose significant risks to the environment via the bathing of pets, pets swimming in waterways, and pet waste.

J. Michael Kelley... stated, "Such excessive data requirements may force the voluntary withdrawal of the limited-use MUPs, which would certainly be an unnecessary economic hardship for those primary registrants."

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<sup>14</sup> May 4, 2011 memorandum from Edward Odenkirchen and Stephen Wente (EFED) to Susan Bartow and Eric Olson (Risk Management and Implementation Branch IV) through Nancy Andrews and Sujatha Sankula (EFED) entitled "Regulation review – Preliminary problem formulation for ecological risk and environmental fate, endangered species, and drinking water assessments for fipronil (PC Code 129121; DP 387319)".

Pesticide registration must come with accountability. The additional data requirements that were proposed in the registration review summary are warranted for all residential uses of fipronil. (James TerBush, BioSpotVictims.org, p. 1)

**EPA Response:** The Environmental Fate and Effects Division (EFED) defers to the Pesticide Re-evaluation Division (PRD) on these points.

## **Comments on the Risk Assessment Problem Formulation**

### *Use Description*

**Comment:** Documents in the fipronil registration review docket do not properly characterize fipronil's urban uses, particularly its use for structural pest control, which seems to have been omitted from Biological and Economic Analysis Division Chemical Profile-for Registration Review. This omission, which is particularly striking in that it is likely the major use of fipronil nationwide, is reflected in the overview of fipronil usage in the preliminary problem formulation for the ecological risk assessment (p. 11). The problem formulation does not correctly recognize outdoor building perimeter treatments as an existing registered use, nor acknowledge that this use is intended to control a variety of nuisance insects (not just termites). Full descriptions of fipronil's urban use will facilitate development of an appropriate approach for the exposure assessment.

It is essential for U.S. EPA to expand its workplan to address all outdoor urban uses of fipronil, including but not limited to broadcast applications on impervious surfaces around buildings. This should involve inclusion of urban land uses and applications to impervious surfaces in the pesticide runoff model, and use of a modeling approach appropriate for urban areas.

Urban runoff modeling should account for the elevated washoff of fipronil from treated impervious surfaces. A recent paper by Jiang et al. (2010)<sup>15</sup> specifically examined washoff of fipronil from urban impervious surfaces. Two findings of this paper are notable: the high fraction of fipronil that could be washed off in the first few days after application and the long period of time during which residual wash-off persisted (>100 days). (California Stormwater Quality Association, p. 7)

**Comment:** The overview of fipronil usage in the preliminary problem formulation for the ecological risk assessment (p. 11) does not recognize outdoor building perimeter treatments as an existing registered use that is intended to control a variety of nuisance insects. It is imperative that the workplan address all outdoor urban uses of fipronil, including but not limited to broadcast applications on impervious surfaces around buildings. A recent study<sup>12</sup> found that a high fraction of fipronil could be washed off in the first few days after application and residual wash-off continued for over 100 days. (California Regional Water Quality Control Board, San Francisco Bay Region, p. 3)

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<sup>15</sup> Jiang, W., K. Lin, et al. (2010). "Wash-off potential of urban use insecticides on concrete surfaces." *Environmental Toxicology and Chemistry* 29(6): 1203-1208.



**EPA Response:** The Agency will review the references cited. Outdoor perimeter treatments will be assessed in the risk assessment. EFED will incorporate better descriptions of this use into the risk assessment.

**Comment:** On pages 10 and 11 of the summary document, the Agency has requested specific information and data to help in refining the risk assessments for fipronil. The following comments address EPA's request: Please note that our responses are grouped into 3 different product types – Granular Products, Bait Gel Products, and Bait Station products for which each of the product types has distinct yet similar use patterns

**EPA Response:** Bayer CropScience (BCS) has provided detailed information on these product types on pages 12-15 of their comments. The agency greatly appreciates this information and will use it to refine the final risk assessment.

### *Conceptual Model*

**Comment:** Both the risk hypothesis (p. 23) and conceptual model (p. 24) need to identify fipronil applications on impervious surfaces and transport to surface waters in urban runoff via impervious storm drain systems as having the potential to cause reduced survival, growth, reproduction, and other adverse effects to non-target aquatic organisms. ...impervious surfaces and paved/piped urban storm drainage systems facilitate expedient wash-off and transport of pollutants like fipronil, carrying them quickly and efficiently away from application locations and into receiving water.

U.S. EPA's recent ecological risk assessment problem formulations for pyrethroids (e.g., gamma and lambda cyhalothrin) provide examples of risk hypotheses and conceptual models that appropriately recognize impervious surface applications and storm drain transport pathways. (California Stormwater Quality Association, p. 6 and 7)

**Comment:** The risk hypothesis (p. 23) and conceptual model (p. 24) fail to identify fipronil applications to impervious surfaces, resulting in transport of fipronil to surface waters via urban runoff, as having the potential to cause reduced survival, growth, reproduction, and other adverse effects to non-target aquatic organisms. We urge EPA to consider the extensive scientific literature on this topic that CASQA is submitting, and to incorporate CASQA's conceptual model into its assessment.

We also encourage EPA to use its recent ecological risk assessment problem formulations for pyrethroids (e.g., gamma and lambda cyhalothrin) as examples of risk hypotheses and conceptual models that appropriately recognize impervious surface applications and storm drain transport pathways. (California Regional Water Quality Control Board, San Francisco Bay Region, p. 3)

**Comment:** Environmental monitoring data demonstrate that fipronil is likely transported to surface waters through both water and sediment transport. The environmental fate and transport sections of the problem formulation (pp. 12 and 18) needs revision to reflect

fipronil's environmental mobility, urban application patterns, and both water and sediment transport pathways. (California Stormwater Quality Association, p. 8)

**EPA Response:** The conceptual model and risk hypotheses will be modified for the risk assessment to be consistent with the pyrethroid problem formulations.

**Comment:** We support the inclusion of fipronil degradates in the ecological risk assessment; however, the basis for selection of only three of fipronil's degradates for inclusion in the ecological risk assessment is unclear. Might other degradates contribute to fipronil's aquatic toxicity? The lack of monitoring data for other degradates may reflect that they have not been on the list of analytes, and should not necessarily be taken to mean that they are not environmentally meaningful.

Three fipronil degradates are persistent in aquatic sediments. Lin et al. (2009) determined that fipronil degradates are very persistent in aquatic sediments, where they have half-lives of hundreds of days.... The problem formulation should be revised to recognize this unusual persistence. Because aquatic sediments differ from rice fields, the "aquatic field dissipation" data in the problem formulation (p. 17) should not be used to represent fipronil degradation rates in surface water sediments. (California Stormwater Quality Association, p. 8 and 9)

**EPA Response:** The three degradates for which additional data was sought (fipronil sulfide (MB 45950), fipronil sulfone (MB 46136), and MB 46513) are considered to be the most toxic degradates based on their chemical structures (presence of a cyano-group) that are produced in major quantities (defined as greater than 10% of the parent chemical applied) in any of the submitted fate studies. Some of the data requested in the problem formulation (aerobic and anaerobic aquatic metabolism studies) should accurately reflect the persistence of the fipronil degradates in aquatic sediments. The inputs from these studies are used in a standard model (EXAMS) to assess risks posed by the persistence of both the parent (fipronil) and degradates. The default assumption for degradation pathways for which no data is available is that the chemical is stable (does not degrade).

### *Modeling*

**Comment:** We understand that U.S. EPA prefers to use its existing PRSM/EXAMS model rather than a model that is specifically designed to address pollutants in urban runoff. We agree that this model has potential to be implemented in a manner that would provide meaningful information for pesticide ecological risk assessments. However, U.S. EPA needs to work on the way the model is set up to make the modeling exercise more informative for its risk assessments and risk management decisions. As we have previously explained in detail,<sup>16</sup> we suggest that U.S. EPA consider alternatives to the "impervious scenario" used in its model, as we believe there are better ways to represent urban watersheds that will generate more realistic and useful modeling results for U.S. EPA risk managers. U.S. EPA has several years (while it awaits receipt of data required

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<sup>16</sup> CASQA Comments on Gamma and Lambda Cyhalothrin Registration Review (2011), Docket ID Numbers EPA-HQ-OPP-2010-0479 and EPA-HQ-OPP-2010-0480, February 22.

for the environmental risk assessment) to develop its urban modeling approach. We recommend that U.S. EPA take the same approach for addressing urban areas on a national scale as it did for agricultural areas—develop a suite of urban example scenarios.

U.S. EPA Region 9 is involved in a research project that should provide valuable insights as to how PRSM/EXAMS can be set up to model pesticides in urban runoff. This project, which comes out of the CalFED Bay-Delta Science Program, is modeling pesticides in stormwater runoff from the urbanized portions of the California Bay/Delta region. Information from product labels and applicator surveys (including the enclosed Meta Research, Inc. and Pyrethroid Working Group (2010) report) was used to allocate pesticide applications to buildings, lawns, and other impervious and pervious surfaces. Washoff studies similar to the enclosed Jiang et al (2010) study were used to develop model input parameter values for pesticide washoff from impervious surface applications. The urban portion of the project will be presented at this week's American Chemical Society meeting<sup>17</sup> and will be described in detail in the soon to be published project report.<sup>18</sup> We encourage OPP to contact Debra Denton, U.S. EPA Region 9 (Denton.Debra@epamail.epa.gov) for more information. (California Stormwater Quality Association, p. 7 and 8)

**Comment:** We request that EPA develop alternatives to the “impervious scenario” used in the PRSM/EXAMS model, based on land use conditions that are more representative of urban watersheds; alternative scenarios will generate more realistic and useful modeling results. The current urban impervious surface scenario does not adequately represent today's urban environment of mixed uses that include dense residential with small lot sizes, multifamily, and commercial land uses. These land uses all have significantly more impervious area per acre than the current urban impervious surface scenario. In addition, urban soils are highly compacted. The current scenario most certainly underestimates the mass of pesticide runoff in urban areas. (California Regional Water Quality Control Board, San Francisco Bay Region, p. 3)

**EPA Response:** Urban and suburban watersheds are typically more difficult to model than rural watersheds because of the variety of land uses, inputs of potential contaminants, and pathways to waterbodies of concern. The Agency is aware of limitations to its current urban modeling approach, but unfortunately, has not been able to find any better approach. If evidence exists that the Agency's current method underestimates exposure, the Agency would appreciate receiving that information.

**Comment:** The risks to aquatic ecosystems from concurrent exposure to fipronil and multiple degradates must be evaluated cumulatively. Monitoring data demonstrate that organisms are exposed to all compounds together. The actual risks of fipronil can only be

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<sup>17</sup> Williams, W. M., K. Moran et al. (2011). “Development of a modeling system to estimate pesticide runoff from urban areas in California.” Presented at American Chemical Society 242nd National Meeting, Denver CO, August 30, 2011; paper number AGRO 125.

<sup>18</sup> Hoogeweg, C. G., W. M. Williams et al. (2011). Spatial and Temporal Quantification of Pesticide Loadings to the Sacramento River, San Joaquin River, and Bay-Delta to Guide Risk Assessment for Sensitive Species. Funded by the CalFED Bay Delta Science Program. Prepared for the California Department of Water Resources by Waterborne Environmental, Inc. and U.C. Davis. In preparation.

assessed if the ecological risk assessment accounts for cumulative exposures to all compounds at once. U.S. EPA could use a conservative approach to estimate the cumulative risk by comparing the sum of the estimated concentrations of fipronil plus degradates in surface water to the most sensitive aquatic toxicity values. (California Stormwater Quality Association, p. 9)

**EPA Response:** The Agency is hoping to be able to model chemical (parent and degradates) separately and compare each chemical to its toxicity data as well as combine the exposure estimates and individual chemical toxicity data to provide a risk estimate for the total fipronil residue exposure.

**Comment:** Product formulation should be fully considered in the risk assessment. Product formulation affects the amount of a pesticide that is washed off of treated impervious surfaces when it rains. (California Stormwater Quality Association, p. 10)

**EPA Response:** The Agency is aware of issues regarding formulation effects on wash-off and has recently received a column leaching study for the Termidor® fipronil formulation under a separate action which shows the formulation is much more mobile than the active ingredient alone. Conservative assumptions will be used to account for the enhanced mobility of the formulation.

*Estimating Environmental Concentrations of Fipronil through Publically-owned Treatment Works (POTW)*

**Comment:** The simple method of calculating national average indoor usage and estimating POTW discharge is not going to provide the necessary quality of analysis. Pesticide usage depends on climate, pest pressures, and other regional issues, causing substantial variation in POTW discharges. At present, it is unclear which uses are the source of most fipronil discharges (could be pets or other indoor uses or evaporation into buildings from underground injection or cleanup from outdoor applications). This uncertainty would make it very difficult to determine which uses to include in the estimation. The outcome of such a simple calculation would not be sufficiently robust to form the basis for a decision with such significant financial implications for POTWs.

Further, EPA is asked to recognize cross-media transfer for this pesticide and to assess the environmental and management risks associated with fipronil and its very persistent degradates in sewage sludge ("biosolids"). (Tri-TAC, p. 2 and 3)

**EPA Response:** The Environmental Fate and Effects Division (EFED) defers to the Pesticide Re-evaluation Division (PRD) on these points.

*Down-the-Drain Assessment and Biosolids Land Application*

**Comment:** Tri-TAC requests that EPA modify the use of the "down-the-drain" assessment to evaluate the impacts of fipronil sewer discharges. Although Tri-TAC supports the use of U.S. EPA's standard tool for down-the-drain assessments, Exposure and Fate Assessment Screening Tool (E-FAST) Version 2.0, we have concerns with the

way that OPP has applied E-FAST. In response to past Tri-TAC comments, OPP has proposed to work with Office of Water and stakeholders to refine the way it uses E-FAST.<sup>1</sup> In the past, OPP and OW have used different exposure periods and exposure frequencies in their ecological effects assessments. If these factors are not being addressed in the OPP/OW Common Effects Assessment Methodology project, we request that OPP work with OW to develop a means of avoiding regulatory inconsistencies. One option would be to modify OPP pesticide runoff models to provide exposure estimates for multiple time periods, including time periods consistent with those used by OW. (Tri-TAC, p. 3)

**Comment:** Roughly fifty percent of the total cost of wastewater treatment is expended on solids handling. Land application is a frequently used method for recycling biosolids. Since many pesticides adsorb strongly to organic matter, a portion of fipronil entering POTWs will likely partition into biosolids. As such, the fipronil environmental risk assessment should address biosolids as well as effluent. The analysis of this partitioning has largely been missing from prior studies. We have heard that US EPA is open to including this component of your review and are pleased. (Tri-TAC, p. 3)

**EPA Response:** The Agency commits to using the best available data in developing input parameters for the down-the-drain model. As with the other models described in the Problem Formulation, however, the nationwide scale of the risk assessment will preclude consideration the many flow regimes and removal methods that may apply at a local level. The Agency will characterize the uncertainties in its risk assessment which result, as well as the range of potential vulnerabilities which could impact fipronil exposure from these uses.

Discharge of fipronil and degradates into the environment via effluent will be considered to the best degree possible in the assessment. In addition, the Agency is actively evaluating the extent to which ecological risk from copper via application of biosolids to land should be addressed in its forthcoming copper ecological risk assessment and, by extension, other potential contaminants. As part of this evaluation, OPP is working closely with OW, which regulates land application of biosolids under the Clean Water Act.

#### *Assessment Endpoints*

**Comment:** Assessment endpoints (p. 22) should include sediment-dwelling aquatic organisms in both fresh water and salt (“marine and estuarine”) water. Maul et al (2008) found that *Chironomus tentans* is extremely sensitive to the presence of fipronil and its degradates in aquatic sediments, as summarized in the table below:

**Toxicity of Fipronil and Two Degradates in Sediment to *Chironomus tentans***  
(µg/g organic carbon, dry weight)

Parameter	LC <sub>50</sub>	EC <sub>50</sub> (immobilization)
Fipronil	0.13	0.10
Fipronil sulfone	0.12	0.04
Fipronil sulfide	0.16	0.06

Although aquatic sediment monitoring has been relatively limited, concentrations exceeding the levels in this table have been found in both fresh water (central Texas creeks)<sup>19</sup> and estuarine sediments (Ballona Creek Estuary, Los Angeles).<sup>20</sup>

We support proposed data requirements for whole sediment freshwater and estuarine marine invertebrate toxicity. These requirements should be expanded to include chronic toxicity to ensure that U.S. EPA has the information necessary to complete its risk assessment for this endpoint, which may be the most sensitive aquatic toxicity endpoint due to the persistence of fipronil degradates in aquatic sediments. (California Stormwater Quality Association, p. 9)

**Comment:** U.S. EPA should evaluate sublethal endpoints other than growth and reproduction quantitatively. Other endpoints that merit consideration are swimming performance (see Beggel et al. 2010)<sup>21</sup> and immobilization (see Maul et al. 2008).<sup>22</sup> As Beggel et al (2010) and Maul et al (2008) note, these sublethal effects can significantly affect organism populations. The fish deformities observed by Beggel et al (2010) also merit investigation. We strongly prefer quantitative assessments of these endpoints, instead of the qualitative assessment indicated in the problem formulation (p. 28) to ensure that they are fully considered in risk mitigation design and have equal weight in management decisions. (California Stormwater Quality Association, p. 10)

**Comment:** Product formulation should be fully considered in the risk assessment.... the formulation can also modify toxicity. Beggel et al. (2010)<sup>23</sup> recently demonstrated that exposure to the most heavily used fipronil product, Termidor, affected fish swimming performance much longer than exposure to fipronil by itself. (California Stormwater Quality Association, p. 10)

<sup>19</sup> Hintzen, E. P., M. J. Lydy, et al. (2009). "Occurrence and potential toxicity of pyrethroids and other insecticides in bed sediments of urban streams in central Texas." *Environmental Pollution* 157(1): 110-116.

<sup>20</sup> Bay, S., D. J. Greenstein, et al. (2010). Toxicity Identification Evaluation of Sediment (Sediment TIE) in Ballona Creek Estuary: Final Report. Technical Report 634. Costa Mesa, CA: Southern California Coastal Water Research Project.

[ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/TechnicalReports/634\\_BallonaTIE.pdf](ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/TechnicalReports/634_BallonaTIE.pdf)

<sup>21</sup> Beggel, S., I. Werner, et al. (2010). "Sublethal toxicity of commercial insecticide formulations and their active ingredients to larval fathead minnow (*Pimephales promelas*)." *Science of The Total Environment* 408(16): 3169- 3175.

<sup>22</sup> Maul, J. D., A. A. Brennan, et al. (2008). "Effect of Sediment-Associated Pyrethroids, Fipronil, and Metabolites on *Chironomus Tentans* Growth Rate, Body Mass, Condition Index, Immobilization, and Survival." *Environmental Toxicology and Chemistry* 27(12): 2582-2590.

<sup>23</sup> Beggel, S., I. Werner, et al. (2010). "Sublethal toxicity of commercial insecticide formulations and their active ingredients to larval fathead minnow (*Pimephales promelas*)." *Science of the Total Environment* 408(16): 3169-3175.

**EPA Response:** The Agency has included chironomids in the matrix of available data. The Agency has requested in the past and has evaluated sediment toxicity tests with invertebrates. The problem formulation has identified chronic sediment invertebrate testing data gaps.

With respect to sublethal effects, the Agency will consider the citations provided. Quantitative use of sublethal effects is considered in Agency risk assessments if the endpoints come from whole organism testing, are linked to assessment endpoints of survival and reproduction in a quantitative manner by a peer reviewed method, and available data provide both a no observed effect and lowest observed effect endpoint.

#### *Consistency between EPA Offices*

**Comment:** Integration of exposure and effects (p. 29) should involve the Office of Water (OW). U.S. EPA's OPP is working with OW to establish a common effects assessment methodology. This effort should be far along—if not complete—before U.S. EPA initiates its fipronil environmental risk assessment. We request that the workplan be modified to indicate OPP's intent to work with OW and to utilize the outcomes of the common effects assessment methodology project in fipronil registration review.

To facilitate integration with OW regulatory programs, we request that the work plan be modified to provide exposure estimates for time periods consistent with those used by OW in addition to the time periods ordinarily used by OPP. (California Stormwater Quality Association, p. 10)

**Comment:** ...we request that the work plan be modified to provide exposure estimates for time periods consistent with those used by OW, in addition to the time periods ordinarily used by OPP. (California Regional Water Quality Control Board, San Francisco Bay Region, p. 3)

**EPA Response:** At this time, the OPP/OW common effects methodology framework is under development and a time line to include an integrated methodology in OPP's risk assessment process has not been established. The focus of the OPP/OW common effects methodology project has been on characterizing effects of stressors on aquatic organisms.

#### **Data Requirements**

##### *General Data Requirements*

**Comment:** We particularly support requirements to submit environmental fate and toxicity data for fipronil's environmentally relevant degradates (at a minimum fipronil sulfide, fipronil sulfone, and fipronil desulfinyl). All of these degradates are found to occur in aquatic ecosystems. Any data requirement decision based on an assumption that fipronil sulfone is not a major degradate in aquatic environments (p. 32) should be

revised. (California Regional Water Quality Control Board, San Francisco Bay Region, p. 2)

**EPA Response:** The agency has not eliminated the degradate from the risk assessment.

#### *Fate Data Requirements*

##### General Comments

**Comment:** We strongly support U.S. EPA's proposed environmental fate and aquatic toxicity data requirements, which are essential for U.S. EPA to avoid underestimating fipronil's risks in urban watersheds. We particularly support data requirements for environmental fate and toxicity data for fipronil's environmentally relevant degradates (at a minimum fipronil sulfide, fipronil sulfone, and fipronil desulfinyl). As monitoring data show, all three of these degradates commonly occur in aquatic ecosystems. If any data requirement decisions are based on the incorrect assumption that fipronil sulfone is not a major degradate in aquatic environments (p. 32), these should be revised. (California Stormwater Quality Association, p. 11)

**EPA Response:** The agency has not eliminated the degradates from the risk assessment.

##### EPA Requirement: 835.4400, Anaerobic aquatic metabolism, MB45950

**Comment:** BCS considers this study unnecessary. The behavior of MB45950 is already understood from the anaerobic aquatic study with fipronil. In addition, a higher tier study has been conducted to further understand the degradation of fipronil metabolites in the outdoor environment (MRID 46936101). Water exposure assessment conducted for the metabolites should consider this higher tier study.

Therefore, the behavior of MB45950 in a sediment-water system under anaerobic conditions is already understood in laboratory and outdoor studies, and an additional anaerobic aquatic laboratory study will not provide additional information, nor will it allow appropriate refinement of the exposure. (BCS, p. 6)

**Comment:** The environmental monitoring database for fipronil (and its metabolites and degradates) is extensive. As such there is little to be gained by gathering additional anaerobic aquatic metabolism laboratory data since anaerobic data are not used for risk assessment purposes and, thus, have no impact on risk decisions. Consequently, BASF requests that this EPA-anticipated data requirement be waived.

EPA can review specific relevant data found in the following article from the open literature: Lin K, Haver D, Oki L, and Gan J 2009. Persistence and Sorption of Fipronil Degradates in Urban Stream Sediments. *Environmental Toxicology and Chemistry* Vol. 28, No. 7, pp. 1462-1468. BASF is submitting this report for EPA to review and consider. See Appendix 1. (BASF, p. 12)

**EPA Response:** Fipronil sulfide (MB 45950) concentrations continuously increased in the sediment of the fipronil anaerobic aquatic metabolism study (MRID 43291704). The



referenced “Chipco® Topchoice™ - Effects on Aquatic Fauna in Outdoor Simulated Ponds” (MRID 46936101) produced and apparently degraded fipronil sulfide in its sediment. However, this study is for an aerobic system (at least in the water column) rather than anaerobic. The referenced Lin paper (2009), calculated degradation half-lives of 352, 301, and 219 days for fipronil sulfide under facultative conditions (only partially anaerobic). None of these studies substitutes for an anaerobic aquatic metabolism study. In the absence of an acceptable anaerobic aquatic metabolism study, fipronil sulfide will be considered stable to anaerobic aquatic metabolism.

*EPA Requirement: 835.4400, Anaerobic aquatic metabolism, MB46136*

**Comment:** BCS considers this study unnecessary. The anaerobic aquatic degradation of metabolite MB46136 (sulfone) is expected to be similar to fipronil. In addition, a higher tier study has been conducted to further understand the degradation of fipronil metabolites in the outdoor environment (MRID 46936101). The water exposure assessment conducted for the metabolites should consider the higher tier study.

Therefore, the behavior of MB46136 in a sediment-water system under anaerobic conditions is already understood in laboratory and outdoor studies, and an additional anaerobic aquatic laboratory study will not provide additional information, nor will it allow appropriate refinement of the exposure and risk assessment. (BCS, p. 7)

**Comment:** The environmental monitoring database for fipronil (and its metabolites and degradates) is extensive. As, such there is little to be gained by gathering additional anaerobic aquatic metabolism laboratory data since anaerobic data are not used for risk assessment purposes and, thus, have no impact on risk decisions. Consequently, BASF requests that this EPA-anticipated data requirement be waived.

EPA can review specific relevant data found in the following article from the open literature: Lin K, Haver D, Oki L, and Gan J 2009. Persistence and Sorption of Fipronil Degradates in Urban Stream Sediments. Environmental Toxicology and Chemistry Vol. 28, No. 7, pp. 1462-1468. BASF is submitting this report for EPA to review and consider. See Appendix 1. (BASF, p. 12)

**EPA Response:** Fipronil sulfone (MB 46136) concentrations never exceeded 1% in the sediment or water of the fipronil anaerobic aquatic metabolism study (MRID 43291704). Therefore, it would be difficult to use this study to calculate a half-life useful for modeling. The referenced “Chipco® Topchoice™ - Effects on Aquatic Fauna in Outdoor Simulated Ponds” (MRID 46936101) produced fipronil sulfone in its sediment, but does not yield data from which a half-life can be calculated. Again, this study is for an aerobic system (at least in the water column) rather than anaerobic. The referenced Lin paper (2009), calculated degradation half-lives of 589, 502, and 502 days for fipronil sulfone under facultative conditions (only partially anaerobic). None of these studies substitutes for an anaerobic aquatic metabolism study. In the absence of an acceptable anaerobic aquatic metabolism study, fipronil sulfone will be considered stable to anaerobic aquatic metabolism.

EPA Requirement: 835.4400, Anaerobic aquatic metabolism, MB46513

**Comment:** The aerobic aquatic study conducted for MB46513 (photolysis degradate) showed the compound moves from the water phase to the sediment phase, and degrades slowly via conversion of the cyano moiety to an amide. The cyano-amide conversion occurs under both aerobic and anaerobic conditions. In addition, a higher tier study has been conducted to further understand the degradation of fipronil metabolites in the outdoor environment (MRID 46936101). The water exposure assessment conducted for the metabolites should consider the higher tier study.

Therefore, the behavior of MB46513 in a sediment-water system under anaerobic conditions is already understood in laboratory and outdoor studies, and an additional anaerobic aquatic laboratory study will not provide additional information, nor will it allow appropriate refinement of the exposure and risk assessment. (BCS, p. 7)

**Comment:** The environmental monitoring database for fipronil (and its metabolites and degradates) is extensive. As, such there is little to be gained by gathering additional anaerobic aquatic metabolism laboratory data since anaerobic data are not used for risk assessment purposes and, thus, have no impact on risk decisions. Consequently, BASF requests that this EPA-anticipated data requirement be waived.

EPA can review specific relevant data found in the following article from the open literature: Lin K, Haver D, Oki L, and Gan J 2009. Persistence and Sorption of Fipronil Degradates in Urban Stream Sediments. *Environmental Toxicology and Chemistry* Vol. 28, No. 7, pp. 1462-1468. BASF is submitting this report for EPA to review and consider. See Appendix 1. (BASF, p. 13)

**EPA Response:** The Agency does not have record of receiving an aerobic aquatic metabolism study for MB46513 as described in the BCS comment. In the fipronil anaerobic aquatic metabolism study (MRID 43291704), MB46513 concentrations never exceeded 1% in the sediment or water. Therefore, it would be difficult to use this study to calculate a half-life useful for modeling. The referenced “Chipco® Topchoice™ - Effects on Aquatic Fauna in Outdoor Simulated Ponds” (MRID 46936101) contained MB46513 in its sediment, but does not yield data from which a half-life can be calculated. Again, this study is for an aerobic system (at least in the water column) rather than anaerobic. The referenced Lin paper (2009), calculated degradation half-lives of 497, 217, and 305 days for MB46513 under facultative conditions (only partially anaerobic). None of these studies substitutes for an anaerobic aquatic metabolism study. In the absence of an acceptable anaerobic aquatic metabolism study, MB46513 will be considered stable to anaerobic aquatic metabolism.

*Effects Data Requirements*

General Comments

**Comment:** ...we support proposed data requirements for whole sediment freshwater and estuarine marine invertebrate toxicity. These requirements should be expanded to include chronic toxicity to ensure that EPA has the information necessary to complete its risk

assessment for this endpoint, which may be the most sensitive aquatic toxicity endpoint due to the persistence of fipronil degradates in aquatic sediments. (California Regional Water Quality Control Board, San Francisco Bay Region, p. 2)

**Comment:** Acute and chronic toxicity data for freshwater and estuarine/marine fish and invertebrates are necessary to perform the down-the-drain and biosolids assessments. Tri-TAC recommends that EPA issue data requirements for fipronil that fill any gaps in available data. The data requirements for fipronil should mimic the data requirements for pyrethroids undergoing registration review, which are the minimum necessary for a scientifically sound environmental risk assessment.<sup>24</sup>

Because there are several potential sources of fipronil in POTW discharges, because fipronil has very persistent degradates, and because fipronil is toxic to aquatic organisms at very low concentrations, POTW monitoring is the only means by which it will be possible to determine whether fipronil and its degradates are present in POTW effluent or biosolids at levels that may be environmentally problematic. (Tri-TAC, p. 4)

**EPA Response:** The Agency will consider the uncertainties in basing the risk assessment on extrapolations. If risk managers believe regulatory decisions can be reached using conservative extrapolation methods the Agency may choose not to request data identified in the data gaps section of the problem formulation.

*EPA Requirement: 850.1010, Freshwater invertebrate acute toxicity, MB46513*

**Comment:** Aquatic invertebrates are consistently more sensitive to MB46136 than MB46513. Data already exists comparing the difference in toxicity between MB46136 and MB46513 in mysid shrimp acute tests which is a species sensitive to fipronil. In the mysid shrimp, the MB46513 metabolite was over 10 times less toxic than parent, fipronil. In lieu of requiring a test with MB46513 in daphnids, the toxicity differential between the metabolites in the mysid acute tests can be calculated and applied to the *Daphnia* fipronil value to estimate a value for MB46513. Therefore this study is not needed for the risk assessment and should not be included in a data call-in for fipronil. (BCS, p. 7)

**Comment:** It is not expected that this data requirement will add meaningful information to the risk assessment. The estuarine/marine invertebrate (mysid shrimp) is clearly more sensitive than the freshwater invertebrate (daphnid) with fipronil (parent). Additionally, aquatic invertebrates are consistently more sensitive to MB46136 than MB46513. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 13)

**EPA Response:** The Agency will consider the uncertainties in basing the risk assessment on extrapolations. If risk managers believe regulatory decisions can be reached using conservative extrapolation methods the Agency may choose not to request data identified in the data gaps section of the problem formulation.

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<sup>24</sup> See data requirements in Solliday, A.; Federoff, N. E.; Meléndez, J. L.; U.S. EPA Office of Pesticide Programs Environmental Fate and Effects Division (2010). *Environmental Fate and Ecological Risk Assessment Revised Problem Formulation in Support of Registration Review for Bifenthrin*. December 22.

EPA Requirement: 850.1300, Freshwater Aquatic Invertebrate Life-Cycle, Fipronil sulfide (MB45950)

**Comment:** A freshwater aquatic invertebrate (*Daphnia magna*) life-cycle study was conducted with MB45950 (MRID No. 42918670: McNamara, P. (1990) MB45950 -- Chronic Toxicity to Daphnids (*Daphnia magna*) Under Flow-through Conditions: Final Report: Lab Project Number: 90-4-3292: 10566.1089.6147.130. Unpublished study prepared by Springborn Laboratories Inc. 76p), and reviewed by EPA and considered invalid. However, the EPA reviewer did not have the raw data at the time of the review. At the request of the reviewer, the raw data were subsequently submitted (MRID No. 43291724: Mihaich, E. (1994) Raw Data Submission Pertaining to (MB45950): Chronic Toxicity to Daphnids (*Daphnia magna*) under Flow-Through Conditions: Addendum: Lab Project Number: 90/4/3292. Unpublished study prepared by Rhone-Poulenc Ag Co. 63p.) The results of the data review are unknown and it is not clear if the status of the study changed after EPA reviewed the raw data. BASF requests that EPA review the history of this submission and provide its conclusion to BASF and the public prior to the release of the Final Work Plan.

It should be noted that a NOEC of 13 µg/L was obtained from the original MB45950 study (MRID No. 42918670: McNamara, P. (1990) MB45950 -- Chronic Toxicity to Daphnids (*Daphnia magna*) Under Flow-through Conditions: Final Report: Lab Project Number: 90-4-3292: 10566.1089.6147.130. Unpublished study prepared by Springborn Laboratories Inc. 76p.) A significantly lower NOEC of 0.63 µg/L was obtained from the same type of study conducted with MB46136. As aquatic invertebrates are consistently more sensitive to MB46136 than MB45950, repeating a freshwater aquatic invertebrate life-cycle study with MB45950 is not expected to provide meaningful information for risk assessment purposes. Currently, effect levels listed in the public literature on black fly are driving the risk assessment (refer to Overmyer, J.P., B.N. Mason, K.L. Armbrust. 2005. Acute toxicity of imidacloprid and fipronil to a nontarget aquatic insect, *Simulium vittatum* Zetterstedt cytospecies IS-7. *Bull. Environ. Toxicol.* 74:872-879). Given all the data generated to date, a new study is not expected to provide significant new information. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 14)

**EPA Response:** The Agency will consider the uncertainties in basing the risk assessment on extrapolations. If risk managers believe the regulatory decisions can be reached using conservative extrapolation methods the Agency may choose not to request data identified in the data gaps section of the problem formulation. The Agency will also conduct a search for the supplemental information relative to testing MB950 and will make any appropriate changes to the standing of the original submitted study report.

EPA Requirement: 850.1300, Freshwater Aquatic Invertebrate Life-Cycle, Fipronil sulfone (MB46136)

A freshwater aquatic invertebrate (*Daphnia magna*) life-cycle study was conducted with MB46136 and submitted to EPA (MRID No. 42918672: McNamara, P. (1992) MB46136 -- Chronic Toxicity to Daphnids (*Daphnia magna*) Under Flow-through Conditions: Lab

Project Number: 91-8-3886: 10566.1090.6175.130. Unpublished study prepared by Springborn Laboratories, Inc. 83p.) The raw data were subsequently submitted to EPA (MRID No. 43291725: Mihaich, E. (1994) Raw Data Submission Pertaining to (MB46136): Chronic Toxicity to Daphnids (*Daphnia magna*) under Flow-Through Conditions: Addendum: Lab Project Number: 91/8/3886. Unpublished study prepared by Rhone-Poulenc Ag Co. 62p.) BASF has never received a Data Evaluation Record (DER) from EPA for this study, nor is it mentioned in EPA's Problem Formulation. As such, BASF is unsure of its classification. BASF requests that EPA inform BASF of the status of this study. NOTE: Regardless of the study classification for MRID 43291725, given the relative insensitivity of daphnids, it is not clear to BASF what value these data would contribute to the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 15)

**EPA Response:** The Agency will also conduct a search for the supplemental information relative to testing MB46136 and will make any appropriate changes to the standing of the original submitted study report and report said information to the registrant.

*EPA Requirement: 850.1350, Estuarine / marine invertebrate life cycle, fipronil*

**Comment:** In the original report, "Machado, M. (1995) Fipronil--Chronic Toxicity to Mysids (*Mysidopsis bahia*) Under Flow-Through Conditions: Final Report: Lab Project Number: 95-4-5820: 10566.1294.6353.530. Unpublished study prepared by Springborn Labs, Inc. 107 p., "there was disagreement on the establishment of a NOEC. This was resolved by the memo, "Anthony F. Maciorowski, Chief, Ecological Effects Branch) dated Aug 2, 1996 where EPA established a NOEC. Therefore, a NOEC was established for this study, and a new study is not needed. In addition, a higher-tiered mysid study was conducted and submitted to EPA in August 9, 2005 (MRID 46619103). This study is not described in the problem formulation. A modified mysid life-cycle higher tiered study was designed using an exposure scenario that would more closely represent realistic chronic exposure. As fipronil is expected to readily partition to the sediment, a static water-sediment design was selected. Traditional mysid life-cycle biological parameters of survival, length of time to first brood, reproduction, growth (length and weight), and behavior were measured. To evaluate potential differences in toxicity based on developmental stage of the organism, the test was initiated with both juvenile (<24 hr old) and sexually mature organisms. To add statistical power to the test, 240 mysids (200 juvenile and 40 sexually mature) were exposed at each test concentration and control. Both juvenile and mature mysids were evaluated for reproductive success. Under this realistic exposure scenario, fipronil was much less toxic to mysids. (BCS, p. 8)

**Comment:** A fipronil mysid chronic study (MRID No. 43681201: Machado, M. (1995) Fipronil -- Chronic Toxicity to Mysids (*Mysidopsis bahia*) Under Flow-Through Conditions: Final Report: Lab Project Number: 95-4-5820: 10566.1294.6353.530. Unpublished study prepared by Springborn Labs, Inc. 107p) was submitted to EPA and classified as supplemental. On August 2, 1996 EPA authored a memorandum defining the chronic endpoint from the study and concluding that no new study was required. A copy of this memorandum is attached in Appendix 2.

Additionally, a higher tiered mysid life-cycle study (MRID No. 46619103: Cafarella, M. (2005) Fipronil - Life-Cycle Toxicity Test with Mysids (*Americamysis bahia*) Under Static Conditions in a Water Sediment System. Project Number: 986/6163, 198247, 2005/5000047. Unpublished study prepared by Springborn Smithers Laboratories. 68 p) was conducted and submitted for EPA review. This study, which EPA did not mention in the Problem Formulation, was run under more environmentally realistic conditions, resulted in an NOEC twelve times higher than the one from the original study. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 15 and 16)

**EPA Response:** The Agency will review the files for the Anthony F. Maciorowski memorandum and will make any necessary changes to evaluated data sets.

With regards to the sediment/water test, the Agency will consider the data in the context of repeat exposures anticipated with new introductions of fipronil and degradates as added into aquatic systems with each runoff exposure event. A static system using a single pesticide introduction to water may or may not represent these exposure conditions.

EPA Requirement: 850.1350, Estuarine / marine invertebrate life cycle, MB46513

**Comment:** This study is not necessary as it will not inform the risk assessment. Aquatic invertebrates are consistently more sensitive to MB46136 than MB46513. Extrapolation of the mysid data suggests the chronic NOEC in daphnids for MB46513 would be a factor of 26 larger than the NOEC for MB46136. Therefore, this study should not be included in a data call-in for fipronil. (BSC, p. 8)

**Comment:** Aquatic invertebrates are consistently more sensitive to MB46136 than MB46513. The NOEC for MB46513 is expected to be at least an order of magnitude greater than the NOEC for MB46136. If conducted, data from a mysid life-cycle with MB46513 is not expected to inform the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 16)

**EPA Response:** The Agency will consider the uncertainties of basing the risk assessment on extrapolations. If risk managers believe the regulatory decisions can be reached using conservative extrapolation methods the Agency may choose not to request data identified in the data gaps section of the problem formulation.

EPA Requirement: 850.1400/1500, Freshwater fish early life stage/full life cycle, MB45950 and MB46136

**Comment (850.1400 Freshwater Fish Early Life Stage MB45950):** These studies are not needed. These metabolites were formed during a fish (bluegill sunfish) bioaccumulation study (MRID 43291706) and would have been formed via metabolism during the estuarine marine fish full life cycle study with parent fipronil (MRID 45265101). Therefore, chronic tests with fipronil parent in fish also include exposure to MB45950 and MB46136. Since these data are already available, the study should not be included in a data call-in for fipronil. (BCS, p. 8)

**Comment:** The fipronil metabolite MB45950 was identified in freshwater bioaccumulation studies (MRID No. 43291706: Chapleo, S.; Hall, B. (1992) (Carbon 14)-MB46030: Bioaccumulation Test in Bluegill Sunfish: Lab Project Number: 381457: 8892. Unpublished study prepared by Inveresk Research International. 95p; MRID No. 43291707: Roohi, A.; Coote, A.; Savage, E. (1993) (Carbon 14) MB46030: Investigation into the Nature and Possible Structures of Metabolites in Fish used in a Bioaccumulation Study at Inveresk Research International (Study IRI/381457): Lab Project Number: P/92/302. Unpublished study prepared by Rhone-Poulenc Agriculture Ltd. 62p; and MRID No. 44298002: Theissen, R. (1997) Fipronil (MB46030): Bioaccumulation in Bluegill Sunfish: Supplemental Response for Storage Stability Data (for MRID Nos. 43291706 & 43291707): Lab Project Number: IRI 381457: RPAL P92/302: IRI 381457/RPAL/P92/302. Unpublished study prepared by Rhone-Poulenc Ag Co. 8p) and would have also been formed via metabolism during the freshwater fish early life stage study (MRID No. 42918627: Machado, M. (1992) MB46030 - The Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) during an Early Life-stage Exposure: Amended Final Report: Lab Project Number: 92-1-4084:10566. 0391.6209.121. Unpublished study prepared by Springborn Laboratories, Inc. 81p) with fipronil (parent). Given that each of these studies resulted in exposure to MB45950, this data requirement would not result in new information and should not be required. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 16 and 17)

**Comment (850.1400 Freshwater Fish Early Life Stage MB46136):** Fipronil metabolite MB46136 was identified in freshwater bioaccumulation studies (MRID No. 43291706: Chapleo, S.; Hall, B. (1992) (Carbon 14)-MB46030: Bioaccumulation Test in Bluegill Sunfish: Lab Project Number: 381457: 8892. Unpublished study prepared by Inveresk Research International. 95p; MRID No. 43291707: Roohi, A.; Coote, A.; Savage, E. (1993) (Carbon 14) MB46030: Investigation into the Nature and Possible Structures of Metabolites in Fish used in a Bioaccumulation Study at Inveresk Research International (Study IRI/381457): Lab Project Number: P/92/302. Unpublished study prepared by Rhone-Poulenc Agriculture Ltd. 62p; and MRID No. 44298002: Theissen, R. (1997) Fipronil (MB46030): Bioaccumulation in Bluegill Sunfish: Supplemental Response for Storage Stability Data (for MRID Nos. 43291706 & 43291707): Lab Project Number: IRI 381457: RPAL P92/302: IRI 381457/RPAL/P92/302. Unpublished study prepared by Rhone-Poulenc Ag Co. 8p) and would have also been formed via metabolism during the freshwater fish early life stage study (MRID No. 42918627: Machado, M. (1992) MB46030 - The Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) during an Early Life-stage Exposure: Amended Final Report: Lab Project Number: 92-1-4084:10566. 0391.6209.121. Unpublished study prepared by Springborn Laboratories, Inc. 81p) with fipronil (parent). Given that each of these studies resulted in exposure to MB46136, this data requirement would not result in new information and should not be required. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 17)

**Comment (850.1400 Freshwater Fish Early Life Stage MB46513):** If this data requirement is requested in the Data Call-In, BASF recommends testing the sheephead

minnow in lieu of the fathead minnow as freshwater and marine fish species are nearly equally sensitive to fipronil and its metabolites and degrades and there is more relevant data for the sheepshead minnow than fathead minnow. (BASF, p. 18)

**Comment** (850.1500 *Estuarine Marine Fish Early Life Stage MB45950*): MB45950 was formed during a fish (bluegill sunfish) bioaccumulation study and would have also been formed via metabolism (and consequently tested, albeit indirectly) during the estuarine marine fish early life stage studies with fipronil (parent) (MRID No. 44605501: Sousa, J. (1998) Fipronil Technical-Early Life-Stage Toxicity Test with Sheepshead Minnow (*Cyprinodon variegatus*): Final Report: Lab Project Number: 96-12-6799: 10566.0796.6402.520. Unpublished study prepared by Springborn Laboratories, Inc. 89p) and fish full life-cycle (MRID No. 45265101: Dionne, E. (2000) Fipronil-Chronic Toxicity to the Sheepshead Minnow (*Cyprinodon variegatus*) During a Full Life-Cycle Exposure: Lab Project Number: 10566.6580: 16958. Unpublished study prepared by Springborn Laboratories, Inc. 469p.) Additionally, the acute LC50 values for MB45950, MB46513 and MB46136 are nearly identical for the trout; the acute LC50 values for MB46513 and MB46136 are nearly identical for the bluegill; and the acute LC50 value for fipronil (parent) in the sheepshead minnow falls between the LC50 values for the bluegill and trout. Taken together, these data suggest that the results of an estuarine marine fish early life stage study with MB45950 will be similar to those with MB46513, which should be an appropriate surrogate for the other metabolites. Since BASF agrees with EPA that an estuarine/marine fish early life stage study with MB46513 should be conducted, BASF requests that the EPA-anticipated data requirement for MB45950 be waived. (BASF, p. 18)

**Comment** (850.1500 *Estuarine Marine Fish Early Life Stage MB46136*): MB46136 was formed during a fish (bluegill sunfish) bioaccumulation study and would have also been formed via metabolism (and consequently tested, albeit indirectly) during the estuarine marine fish early life stage studies with fipronil (parent) (MRID No. 44605501: Sousa, J. (1998) Fipronil Technical-Early Life-Stage Toxicity Test with Sheepshead Minnow (*Cyprinodon variegatus*): Final Report: Lab Project Number: 96-12-6799: 10566.0796.6402.520. Unpublished study prepared by Springborn Laboratories, Inc. 89p) and fish full life cycle (MRID No. 45265101: Dionne, E. (2000) Fipronil-Chronic Toxicity to the Sheepshead Minnow (*Cyprinodon variegatus*) During a Full Life-Cycle Exposure: Lab Project Number: 10566.6580: 16958. Unpublished study prepared by Springborn Laboratories, Inc. 469p.) Additionally, the acute LC50 values for MB45950, MB46513 and MB46136 are nearly identical for the trout; the acute LC50 values for MB46513 and MB46136 are nearly identical for the bluegill; and the acute LC50 value for fipronil (parent) in the sheepshead minnow falls between the LC50 values for the bluegill and trout. Taken together, these data suggest that the results of an Estuarine Marine Fish Early Life Stage study with MB46136 will be similar to those with MB46513, which should be an appropriate surrogate for the other metabolites. Since BASF agrees with EPA that an estuarine/marine fish early life stage study with MB46513 should be conducted, BASF requests that the EPA-anticipated data requirement for MB45950 be waived. (BASF, p. 19)



**EPA Response:** In the absence of the data requested, the Agency will consider the BCF results as a line of evidence for determining appropriate endpoints from existing effects data. Options may include but not be limited to a approach where (1) functional stability of the parent and primary degradates whereby degradation to degradates does not represent a reduction in the toxic potency of the introduced material to the environment or (2) assuming the observed toxicity in available studies is attributable to an estimated organism exposure to the toxic metabolites in accordance with the proportion of their detection in the BCF study.

*EPA Requirement: 850.1730, Bioaccumulation in fish, MB45950 and MB46136*

**Comment:** This study is not scientifically justified because there is information on residue levels and depuration of MB45950 and MB46136 from the fipronil bioconcentration (BCF) study (MRID 43291706). These metabolites have already been tested for their bioaccumulation potential. Metabolites MB46136 and MB45950 were present in the fipronil BCF study in all analyzed tissues. Fipronil and metabolites MB46136 and MB45950 were rapidly eliminated. Therefore, the findings indicate that the low potential for bioaccumulation reported for fipronil (BCF=321) was tested and confirmed for metabolites MB46136 and MB45950. Further supporting this case is the fact that MB46136 and MB45950 are common metabolites found in metabolism studies with other vertebrates (goat and hen MRID 43401105 and 43401106, respectively). The rapid and extensive clearance of residues of MB46136 and MB45950 observed in fish is consistent with the elimination pattern in other vertebrates. These studies should not be included in a data call-in for fipronil. (BCS, p. 9)

**Comment (850.1730 Bioaccumulation in Fish MB45950):** Information on residue levels and depuration of MB45950 is available in the fipronil (parent) bioconcentration reports (MRID No. 43291706: Chapleo, S.; Hall, B. (1992) (Carbon 14)-MB46030: Bioaccumulation Test in Bluegill Sunfish: Lab Project Number: 381457: 8892. Unpublished study prepared by Inveresk Research International. 95p; MRID No. 43291707: Roohi, A.; Coote, A.; Savage, E. (1993) (Carbon 14) MB46030: Investigation into the Nature and Possible Structures of Metabolites in Fish used in a Bioaccumulation Study at Inveresk Research International (Study IRI/381457): Lab Project Number: P/92/302. Unpublished study prepared by Rhone-Poulenc Agriculture Ltd. 62p; and MRID No. 44298002: Theissen, R. (1997) Fipronil (MB 46030): Bioaccumulation in Bluegill Sunfish: Supplemental Response for Storage Stability Data (for MRID Nos. 43291706 & 43291707): Lab Project Number: IRI 381457: RPAL P92/302: IRI 381457/RPAL/P92/302. Unpublished study prepared by Rhone-Poulenc Ag Co. 8p.) The data indicate that the metabolites MB46136 and MB45950 were found at significant levels in all analyzed tissues. Additionally, fipronil (parent) and the metabolites MB46136 and MB45950 were rapidly eliminated. Therefore, the findings of the two reports indicate that the potential for bioaccumulation reported for fipronil (parent) (BCF=321) was tested and confirmed for the metabolites MB46136 and MB45950.

Furthermore, MB46136 and MB45950 are common metabolites found in metabolism studies with other vertebrates (rat, goat and hen). The rapid and extensive clearance of

residues of MB46136 and MB45950 observed in fish is consistent with the elimination pattern in other vertebrates.

Additional aquatic bioconcentration testing with MB45950 is not expected to yield data that will be pertinent to the risk assessment of fipronil. BASF requests that this EPA-anticipated data requirement for MB46136 be waived. (BASF, p. 19 and 20)

**Comment** (850.1730 *Bioaccumulation in Fish MB46136*): Information on residue levels and depuration of MB46136 is available in the fipronil parent bioconcentration reports (MRID No. 43291706: Chapleo, S.; Hall, B. (1992) (Carbon 14)-MB46030: Bioaccumulation Test in Bluegill Sunfish: Lab Project Number: 381457: 8892. Unpublished study prepared by Inveresk Research International. 95p; MRID No. 43291707: Roohi, A.; Coote, A.; Savage, E. (1993) (Carbon 14) MB46030: Investigation into the Nature and Possible Structures of Metabolites in Fish used in a Bioaccumulation Study at Inveresk Research International (Study IRI/381457): Lab Project Number: P/92/302. Unpublished study prepared by Rhone-Poulenc Agriculture Ltd. 62p; and MRID No. 44298002: Theissen, R. (1997) Fipronil (MB 46030): Bioaccumulation in Bluegill Sunfish: Supplemental Response for Storage Stability Data (for MRID Nos. 43291706 & 43291707): Lab Project Number: IRI 381457: RPAL P92/302: IRI 381457/RPAL/P92/302. Unpublished study prepared by Rhone-Poulenc Ag Co. 8p.) The data indicate that the metabolites MB46136 and MB45950 were found at significant levels in all analyzed tissues. Additionally, fipronil (parent) and the metabolites MB46136 and MB45950 were rapidly eliminated. Therefore, the findings of the two reports indicate that the potential for bioaccumulation reported for fipronil (parent) (BCF=321) was tested and confirmed for the metabolites MB46136 and MB45950.

Furthermore, MB46136 and MB45950 are common metabolites found in metabolism studies with other vertebrates (rat, goat and hen). The rapid and extensive clearance of residues of MB46136 and MB45950 observed in fish is consistent with the elimination pattern in other vertebrates.

Additional aquatic bioconcentration testing with MB46136 is not expected to yield data that will be pertinent to the risk assessment of fipronil. BASF requests that this EPA-anticipated data requirement for MB46136 be waived. (BASF, p. 20 and 21)

**EPA Response:** The Agency agrees with the rationale for these waivers.

*EPA Requirement: 850.1730, Bioaccumulation in fish, MB46513*

**Comment:** The bioaccumulation potential of fipronil and metabolites MB46136 and MB45950 has already been tested (MRID 43291706). The metabolite MB46513 has a similar chemical structure and slightly lower log Pow (MB46513 = 3.4) than the other three compounds tested (Fipronil = 3.5-4.0; MB46136 = 3.8; MB45950 = 3.7). Therefore, it is reasonable to assume that MB46513 will share the same properties and the low potential to bioaccumulate. The study should not be included in a data call-in for fipronil.

Note: EPA has suggested that multiple avian studies may be required by data call-in. In many cases in the comments below, these studies will add no useful information to the risk assessment. In that case, animal welfare consideration should be given to the requirement. If all of these studies are required, it could result in the unnecessary sacrifice of over 1000 adult birds and approximately 20,000 hatchlings. (BCS, p. 9)

**Comment:** The bioaccumulation potential of fipronil (parent) and the metabolites MB46136 and MB45950 has been tested and has proven to be low. MB46513 has a similar chemical structure and slightly lower log Pow (MB46513 = 3.4) than the other three compounds tested (fipronil (parent) = 3.5-4.0, MB46136 = 3.8, and MB45950 = 3.7). Therefore, it is reasonable to assume that MB46513 will not bioaccumulate. Consequently, the need for this study is not scientifically justified. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 21)

**EPA Response:** The Agency agrees with the rationale for these waivers.

*EPA Requirement: 850.1735, Whole sediment acute freshwater invertebrate toxicity, MB45950, MB46136, MB46513*

**Comment (MB45950):** BASF directs EPA to the following previously submitted study to address guideline 850.1735, MRID No. 45084801 (Putt, A. (2000) (Carbon-14) MB 45950-Toxicity to Midge (Chironomus tentans) during a 10-Day Sediment Exposure: Lab Project Number: 10566.6536: 10397. Unpublished study prepared by Springborn Labs., Inc. 74p.) (BASF, p. 22)

**Comment (MB46136):** BASF directs EPA to the following previously submitted study to address guideline 850.1735, MRID No. 45175901 (Putt, A. (2000) (Carbon-14) MB 46136-Toxicity to Midge (Chironomus tentans) during a 10-Day Sediment Exposure: Lab Project Number: 10566.6537: 16450. Unpublished study prepared by Springborn Labs., Inc. 72p.) (BASF, p. 22)

**Comment (MB46513):** BASF directs EPA to the following previously submitted study to address guideline 850.1735, MRID No. 45375901 (Putt, A. (2001) (Carbon-14) MB 46513-Toxicity to Midge (Chironomus tentans) during a 10-Day Sediment Exposure: Lab Project Number: 10566.6538: 17490: 102198/OPPTS/128. Unpublished study prepared by Springborn Labs., Inc. 76p.) (BASF, p. 22)

**EPA Response:** The Agency has expanded the suite of species required for sediment toxicity evaluation. The submitted studies do not require repeating. However the additional species represent a data gap until tested.

*EPA Requirement: 850.2100, Avian oral (house sparrow), MB46513, MB46136, MB45950*

**Comment:** These studies are not necessary as it will not provide meaningful information for risk assessment purposes. The house sparrow is much less sensitive than the quail. Comparative quail and house sparrow acute oral studies with fipronil resulted in LD50

values of 11.3 and 1120 mg ai/kg bw, respectively (MRID 42918617 and 42918618). These studies should not be included in a data call-in for fipronil. (BCS, p. 9)

**Comment (MB46513):** Avian oral reports for both quail (MRID No. 43776601: Pedersen, C.; Solatycki, A. (1993) MB46513: 21-Day Acute Oral LD50 Study in Bobwhite Quail: Lab Project Number: 108-017-03. Unpublished study prepared by Bio-Life Associates, Ltd. 62p) and mallard (MRID No. 43776602: Helsten, B.; Solatycki, A. (1994) 14-Day Acute Oral LD50 Study with MB46513 in Mallard Ducks: Lab Project Number: 108-027-04. Unpublished study prepared by Bio-Life Associates, Ltd. 58p) were submitted to the Agency on 08/18/1995. As such, BASF requests that EPA review these previously submitted studies and remove this EPA-anticipated data requirement. (BASF, p. 22 and 23)

**Comment (MB45950):** There is an important pattern with regard to the sensitivity of organisms to fipronil (parent) and its metabolites and degrades: “If an organism is sensitive to fipronil (parent) it is also sensitive to its metabolites and degrades. Conversely, if an organism is less sensitive to fipronil (parent) it is also less sensitive to its metabolites and degrades”.

The bobwhite quail is clearly the most sensitive avian species tested to date. Comparative quail and house sparrow acute oral studies with fipronil (parent) resulted in LD50 values which find the quail being 100 times more sensitive than the sparrow. Since the quail is clearly more sensitive than the house sparrow to fipronil (parent), it follows that the same pattern would hold true for the metabolites and degradates of fipronil.

Therefore, this study is not necessary as it will not provide meaningful information for risk assessment purposes. Additionally, conducting this study would require the unnecessary use and subsequent death of at least 60 birds. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 23)

**Comment (MB46136):** There is an important pattern with regard to the sensitivity of organisms to fipronil (parent) and its metabolites and degrades: “If an organism is sensitive to fipronil (parent) it is also sensitive to its metabolites and degrades. Conversely, if an organism is less sensitive to fipronil (parent) it is also less sensitive to its metabolites and degrades”.

The bobwhite quail is clearly the most sensitive avian species tested to date. Comparative quail and house sparrow acute oral studies with fipronil (parent) resulted in LD50 values which find the quail being 100 times more sensitive than the sparrow. Since the quail is clearly more sensitive than the house sparrow to fipronil (parent), it follows that the same pattern would hold true for the metabolites and degradates of fipronil.

Therefore, this study is not necessary as it will not provide meaningful information for risk assessment purposes. Additionally, conducting this study would require the unnecessary use and subsequent death of at least 60 birds. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 23 and 24)

**Comment (MB46513):** There is an important pattern with regard to the sensitivity of organisms to fipronil (parent) and its metabolites and degrades: “If an organism is sensitive to fipronil (parent) it is also sensitive to its metabolites and degrades. Conversely, if an organism is less sensitive to fipronil (parent) it is also less sensitive to its metabolites and degrades”.

The bobwhite quail is clearly the most sensitive avian species tested to date. Comparative quail and house sparrow acute oral studies with fipronil (parent) resulted in LD50 values which find the quail being 100 times more sensitive than the sparrow. Since the quail is clearly more sensitive than the house sparrow to fipronil (parent), it follows that the same pattern would hold true for the metabolites and degradates of fipronil.

Therefore, this study is not necessary as it will not provide meaningful information for risk assessment purposes. Additionally, conducting this study would require the unnecessary use and subsequent death of at least 60 birds. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 24)

**EPA Response:** Other comments submitted discussed the potential for the combined effects of parent and metabolites in existing avian toxicity data because of the observed endogenous production of metabolites exhibited in chicken metabolism studies. If this is accepted, then a pathway for describing galliforme enhanced sensitivity to fipronil in galliformes is plausible and this galliforme metabolism to potentially toxic degradates may explain the higher sensitivity of tested galliformes when compared to other birds. However, direct environmental exposure to degradates may bypass any metabolic differences among birds and so it is important to understand if the metabolites are toxic in their own right in bird species where metabolism information is lacking.

EPA Requirement: 850.2300, Avian reproduction (quail), MB45950, MB46136

**Comment:** These studies are not needed. This metabolite was formed during a hen metabolism study (MRID 43401106), and therefore would be formed (and consequently tested indirectly) during a quail reproduction study with parent fipronil. These studies should not be included in a data call-in for fipronil. (BCS, p. 10)

**Comment (MB45950):** MB45950 was formed during a fipronil (parent) hen metabolism study (MRID No. 43401106: Stewart, F. (1994) (Carbon 14)-MB46030: Distribution, Metabolism, and Excretion Following Multiple Oral Administration to the Laying Hen: Revised Final Report: Lab Project Number: 68/120R-1011. Unpublished study prepared by Hazleton Europe. 273p) and therefore would be formed (and consequently tested, albeit indirectly) during a quail reproduction study with fipronil (parent). Conducting this study would not provide additionally relevant data and would require the unnecessary use and subsequent death of many birds. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 24 and 25)

**Comment (MB46136):** MB46136 was formed during a fipronil (parent) hen metabolism study (MRID No. 43401106: Stewart, F. (1994) (Carbon 14)-MB46030: Distribution,

Metabolism, and Excretion Following Multiple Oral Administration to the Laying Hen: Revised Final Report: Lab Project Number: 68/120R-1011. Unpublished study prepared by Hazleton Europe. 273p) and therefore would be formed (and consequently tested, albeit indirectly) during a quail reproduction study with fipronil (parent). Conducting this study would not provide additionally relevant data and would require the unnecessary use and subsequent death of many birds. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 25)

**EPA Response:** The comment suggests a hypothesis of combined effects of parent and metabolites in existing avian toxicity data because of the potential for endogenously produced metabolites as exhibited in chicken metabolism studies. If this is accepted, then a pathway for describing galliforme enhanced sensitivity to fipronil in galliformes is plausible and this galliforme metabolism to potentially toxic degradates may explain the higher sensitivity of tested galliformes when compared to other birds. However, direct environmental exposure to degradates may bypass any metabolic differences among birds and so it is important to understand if the metabolites are toxic in their own right in bird species where metabolism information is lacking.

In the absence of direct testing of the metabolites alone, the Agency may select other options to assessments compounds which may include but not be limited to (1) a total toxic residues approach assuming equivalent toxicity of all residues of concern and the parent compound or (2) adjusting the existing fipronil-based effects thresholds downward to reflect an assumption that effects observed are related to the proportion of metabolite expected to be present in the studies organism.

*EPA Requirement: 850.2300, Avian reproduction (quail), MB46513*

**Comment:** This study is not needed. The BCS outdoor uses are formulated or used in such a manner as to not contribute to chronic exposure. Additionally, MB46513 is a minor terrestrial metabolite. This study should not be included in a data call-in for fipronil. (BCS, p. 10)

**Comment (MB46513):** MB46513 is a minor photolytic degradate of fipronil in terrestrial environments, including relevant avian food items. Sensitive birds (i.e., upland game species) are not expected to be exposed to quantities of MB46513 that would adversely effect their reproduction. Additionally, this study would require the unnecessary use and subsequent death of many birds. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 25)

**EPA Response:** The Agency does not limit risk assessment consideration to major metabolite, but must also consider metabolites of toxicological concern. This metabolite is one of toxicological concern.

The comments suggest a hypothesis of combined effects of parent and metabolites in existing avian toxicity data because of the potential for endogenously produced metabolites as exhibited in chicken metabolism studies. If this is accepted, then a pathway for describing galliforme enhanced sensitivity to fipronil in galliformes is

plausible and this galliforme metabolism to potentially toxic degradates may explain the higher sensitivity of tested galliformes when compared to other birds. However, direct environmental exposure to degradates may bypass any metabolic differences among birds and so it is important to understand if the metabolites are toxic in their own right in bird species where metabolism information is lacking.

In the absence of direct testing of the metabolites alone, the Agency may select other options to assessments compounds which may include but not be limited to (1) a total toxic residues approach assuming equivalent toxicity of all residues of concern and the parent compound or (2) adjusting the existing fipronil-based effects thresholds downward to reflect an assumption that effects observed are related to the proportion of metabolite expected to be present in the studies organism.

*EPA Requirement: 850.2300, Avian reproduction (mallard), MB45950, MB46136*

**Comment:** These studies are not needed. This metabolite was formed during a hen metabolism study (MRID 43401106) and therefore would be formed (and consequently tested) during a quail reproduction study with parent fipronil. In addition, the mallard is much less sensitive than the quail, and the data obtained would not inform the risk assessment. These studies should not be included in a data call-in for fipronil. (BCS, p. 10)

**Comment (MB45950):** MB45950 was formed during a fipronil (parent) hen metabolism study (MRID No. 43401106: Stewart, F. (1994) (Carbon 14)-MB46030: Distribution, Metabolism, and Excretion Following Multiple Oral Administration to the Laying Hen: Revised Final Report: Lab Project Number: 68/120R-1011. Unpublished study prepared by Hazleton Europe. 273p) and therefore would be formed (and consequently tested, albeit indirectly) during a quail reproduction study with fipronil (parent). Conducting this study would not provide additionally relevant data and would require the unnecessary use and subsequent death of many birds. Additionally, mallards are consistently less sensitive than bobwhite quail. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 26)

**Comment (MB46136):** MB46136 was formed during a fipronil (parent) hen metabolism study (MRID No. 43401106: Stewart, F. (1994) (Carbon 14)-MB46030: Distribution, Metabolism, and Excretion Following Multiple Oral Administration to the Laying Hen: Revised Final Report: Lab Project Number: 68/120R-1011. Unpublished study prepared by Hazleton Europe. 273p) and therefore would be formed (and consequently tested, albeit indirectly) during a quail reproduction study with fipronil (parent). Additionally, mallards are consistently less sensitive than bobwhite quail. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 26)

**EPA Response:** The Agency does not limit risk assessment consideration to major metabolite, but must also consider metabolites of toxicological concern. This metabolite is one of toxicological concern.

The comments suggest a hypothesis of combined effects of parent and metabolites in existing avian toxicity data because of the potential for endogenously produced metabolites as exhibited in chicken metabolism studies. If this is accepted, then a pathway for describing galliforme enhanced sensitivity to fipronil in galliformes is plausible and this galliforme metabolism to potentially toxic degradates may explain the higher sensitivity of tested galliformes when compared to other birds. However, direct environmental exposure to degradates may bypass any metabolic differences among birds and so it is important to understand if the metabolites are toxic in their own right in bird species where metabolism information is lacking.

In the absence of direct testing of the metabolites alone, the Agency may select other options to assessments compounds which may include but not be limited to (1) a total toxic residues approach assuming equivalent toxicity of all residues of concern and the parent compound or (2) adjusting the existing fipronil-based effects thresholds downward to reflect an assumption that effects observed are related to the proportion of metabolite expected to be present in the studies organism.

*EPA Requirement: 850.2300, Avian reproduction (mallard), MB46513*

**Comment:** This study is not needed. The BCS outdoor uses of fipronil products are formulated or used in such a manner as to not contribute to chronic exposure. In addition, the mallard is much less sensitive than the Northern bobwhite and the data obtained would not inform the risk assessment. MB46513 is a minor terrestrial metabolite. This study should not be included in a data call-in for fipronil. (BCS, p. 10)

**Comment (MB46513):** MB46513 is a minor photolytic degradate of fipronil (parent) in terrestrial environments. Water fowl are not expected to be exposed to quantities of MB46513 that would adversely effect their reproduction. Additionally, this study would require the unnecessary use and subsequent death of many birds. Mallards are consistently less sensitive than bobwhite quail. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 26 and 27)

**EPA Response:** Mallards are less sensitive acutely than bobwhites. However, the commenters have provided no data, toxicokinetically, biochemically, etc. providing evidence that such acute lethal sensitivity is carried through in chronic endpoints. Indeed information referenced by one commenter suggests that galliforme birds may produce the metabolite MB46513 endogeneously. Is this the case for mallards? It is an important question as this metabolite is appreciably more toxic to other terrestrial vertebrates than parent fipronil. It could be that the apparent difference in galliforme and anseriforme birds acute sensitivity to fipronil is in part or in whole dependent upon production of a toxic metabolite. If this metabolite is produced in the environment outside the organism, then it becomes important to characterize this metabolite's toxicity to organisms not encountering MB46513 endogeneously. While one commenter suggests that waterfowl are not expected to be exposed to quantities of MB513 that would adversely affect reproduction there is no supporting evidence given in terms of a toxicological endpoint to which one would be able to compare exposure data.



In the absence of direct testing of the metabolites alone, the Agency may select other options to assessments compounds which may include but not be limited to (1) a total toxic residues approach assuming equivalent toxicity of all residues of concern and the parent compound or (2) adjusting the existing fipronil-based effects thresholds downward to reflect an assumption that effects observed are related to the proportion of metabolite expected to be present in the studies organism.

*EPA Requirement: 850.3020, honey bee acute contact, fipronil, MB45950, MB46136, MB46513*

**Comment:** The exposure pathway by which bees are exposed to fipronil or metabolites does not appear to exist given the current use patterns. In the assessment performed by EPA for the corn use (PC code 129121 dated November 15, 2001), EPA states that such studies would be necessary to support foliar ground or aerial applications of fipronil. Fipronil has no such registrations in the US. Since the Agency agrees fipronil is non-systemic, these data are not needed for risk assessment. These studies should not be included in a data call-in for fipronil. (BCS, p. 10)

**Comment (MB45950):** Within the current uses, there does not appear to be a relevant route of exposure. It is unclear what value the data from an acute contact study with MB45950 will provide. In the in-furrow corn assessment (PC code 129121, dated November 15, 2001), EPA stated that such a study would be necessary to support foliar ground or aerial applications, of which there are none in the U.S. Since the Agency agrees fipronil is non-systemic, these data will not inform the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 27)

**Comment (MB46136):** Within the current uses, there does not appear to be a relevant route of exposure. It is unclear what value the data from an acute contact study with MB46136 will provide. In the in-furrow corn assessment (PC code 129121, dated November 15, 2001), EPA stated that such a study would be necessary to support foliar ground or aerial applications, of which there are none in the U.S. Since the Agency agrees fipronil is non-systemic, these data will not inform the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 27)

**Comment (MB46513):** Within the current uses, there does not appear to be a relevant route of exposure. It is unclear what value the data from an acute contact study with MB46513 will provide. In the in-furrow corn assessment (PC code 129121, dated November 15, 2001), EPA stated that such a study would be necessary to support foliar ground or aerial applications, of which there are none in the U.S. Since the Agency agrees fipronil is non-systemic, these data will not inform the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 27 and 28)

**EPA Response:** While the likelihood of exposure to bees is low from seed treatments of nonsystemic pesticides, there are data to indicate that seed treatments can result in drift events when the seed coat is abraded during the seeding process. Bee kills have been reported in Germany in 2008 (11,000 colonies lost), Purdue University in Indiana in

2010, and in Slovenia in 2011 (2,500 colonies lost) from drift of dust from abraded seed coating treatment. Additionally, house perimeter sprays may result in exposure to honey foraging on ornamental plants in residential settings. Residue data collected from national-level surveys indicates residues of fipronil are detected in comb wax (Mullin *et al.* 2010) and it is likely that these residues were brought back to honeybee colonies by the bees.

Mullin, C. A., M. Frazier, J. L. Frazier, S. Ashcraft, R. Simonds, D. vanEngelsdorp, J. Pettis. 2010. High Levels of Miticides and Agrochemicals in North American Apiaries: Implications for Honey Bee Health. PLoSone 5(3): e9754.  
doi:10.1371/journal.pone.0009754

EPA Requirement: 850.3030, honey bee foliage residue toxicity, fipronil, MB45950, MB46136, MB46513

**Comment:** The exposure pathway by which bees are exposed to fipronil or metabolites does not appear to exist given the current use patterns. In the assessment performed by EPA for the corn use (PC code 129121 dated November 15, 2001), EPA states that such studies would be necessary to support foliar ground or aerial applications of fipronil. Fipronil has no such registrations in the US. Since the Agency agrees fipronil is non-systemic, these data are not needed for risk assessment. These studies should not be included in a data call-in for fipronil. (BCS, p. 11)

**Comment (Fipronil):** As there are no currently registered foliar applications of fipronil in the U.S., a relevant route of exposure does not appear to exist. It is unclear what value the data from a honeybee foliage residue study will provide. In the in-furrow corn assessment (PC code 129121, dated November 15, 2001), EPA stated that such a study would be necessary to support foliar ground or aerial applications, of which there are none in the U.S. Since the Agency agrees fipronil is non-systemic, these data will not inform the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 28)

**Comment (MB45950):** As there are no currently registered foliar applications of fipronil in the U.S., a relevant route of exposure does not appear to exist. It is unclear what value the data from a honeybee foliage residue study will provide. In the in-furrow corn assessment (PC code 129121, dated November 15, 2001), EPA stated that such a study would be necessary to support foliar ground or aerial applications, of which there are none in the U.S. Since the Agency agrees fipronil is non-systemic, these data will not inform the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 28)

**Comment (MB46136):** As there are no currently registered foliar applications of fipronil in the U.S., a relevant route of exposure does not appear to exist. It is unclear what value the data from a honeybee foliage residue study will provide. In the in-furrow corn assessment (PC code 129121, dated November 15, 2001), EPA stated that such a study would be necessary to support foliar ground or aerial applications, of which there are none in the U.S. Since the Agency agrees fipronil is non-systemic, these data will not

inform the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 28 and 29)

**Comment (MB46513):** As there are no currently registered foliar applications of fipronil in the U.S., a relevant route of exposure does not appear to exist. It is unclear what value the data from a honeybee foliage residue study will provide. In the in-furrow corn assessment (PC code 129121, dated November 15, 2001), EPA stated that such a study would be necessary to support foliar ground or aerial applications, of which there are none in the U.S. Since the Agency agrees fipronil is non-systemic, these data will not inform the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 29)

**EPA Response:** The Agency requested toxicity of residues on foliage studies since according to the CFR40 Part 158 data requirements, these studies are triggered for outdoor uses where the acute contact toxicity is  $<11 \mu\text{g}/\text{bee}$  and there is potential exposure to honeybees. While the likelihood of exposure to bees is low from seed treatments of nonsystemic pesticides, there are data to indicate that seed treatments can result in drift events when the seed coat is abraded during the seeding process. Bee kills have been reported in Germany in 2008 (11,000 colonies lost), Purdue University in Indiana in 2010, and in Slovenia in 2011 (2,500 colonies lost) from drift of abraded seed coat. Additionally, house perimeter sprays may result in exposure to honey foraging on ornamental plants in residential settings. Residue data collected from national-level surveys indicates residues of fipronil are detected in comb wax (Mullin *et al.* 2010) and it is likely that these residues were brought back to honeybee colonies by the bees.

Mullin, C. A., M. Frazier, J. L. Frazier, S. Ashcraft, R. Simonds, D. vanEngelsdorp, J. Pettis. 2010. High Levels of Miticides and Agrochemicals in North American Apiaries: Implications for Honey Bee Health. *PLoSone* 5(3): e9754.  
doi:10.1371/journal.pone.0009754

*EPA Requirement: 850.3040, field testing for pollinators, fipronil*

**Comment:** The exposure pathway by which bees are exposed to fipronil or metabolites does not appear to exist given the current use patterns. Since the Agency agrees fipronil is non-systemic, these data are not needed for risk assessment. The study should not be included in a data call-in for fipronil. (BCS, p. 11)

**Comment (Fipronil):** As there are no currently registered foliar applications of fipronil in the U.S., a relevant route of exposure does not appear to exist. It is unclear what value the data generated from field testing with pollinators will provide. Since the Agency agrees fipronil is non-systemic, these data will not inform the risk assessment. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 29)

**EPA Response:** The Agency requested toxicity of residues on foliage studies since according to the CFR40 Part 158 data requirements, these studies are triggered for outdoor uses where the acute contact toxicity is  $<11 \mu\text{g}/\text{bee}$  and there is potential exposure to honeybees. While the likelihood of exposure to bees is low from seed

treatments of nonsystemic pesticides, there are data to indicate that seed treatments can result in drift events when the seed coat is abraded during the seeding process. Bee kills have been reported in Germany in 2008 (11,000 colonies lost), Purdue University in Indiana in 2010, and in Slovenia in 2011 (2,500 colonies lost) from drift of abraded seed coat. Additionally, house perimeter sprays may result in exposure to honey foraging on ornamental plants in residential settings. Residue data collected from national-level surveys indicates residues of fipronil are detected in comb wax (Mullin *et al.* 2010) and it is likely that these residues were brought back to honeybee colonies by the bees.

Mullin, C. A., M. Frazier, J. L. Frazier, S. Ashcraft, R. Simonds, D. vanEngelsdorp, J. Pettis. 2010. High Levels of Miticides and Agrochemicals in North American Apiaries: Implications for Honey Bee Health. PLoSone 5(3): e9754.  
doi:10.1371/journal.pone.0009754

*EPA Requirement: 850.4100, Seedling Emergence Tier II, fipronil*

**Comment:** It is unusual that a seedling emergence study be requested for an active ingredient rather than a formulation. An OECD seedling emergence study has been conducted with formulated product (BASF Registration Document No. 2004/1027260 and amendment 2005/1006512) and will be submitted to EPA. As would be expected of an insecticide, effects on terrestrial plants were minimal. BASF requests that EPA review the results of the OECD guideline report. As a report is being submitted, BASF requests that EPA removed this anticipated data requirement. (BASF, p. 29 and 30)

**EPA Response:** The Agency has received a seedling emergence test report and has commenced evaluation.

*EPA Requirement: 850.4150, Vegetative Vigor Tier II, fipronil*

**Comment:** There does not appear to be an exposure pathway that would lead to the exposure of plant foliage to fipronil based on the current registrations. This study should not be included in a data call-in for fipronil. (BCS, p. 11)

**Comment:** It is unusual that a vegetative vigor study be requested for an active ingredient rather than a formulation. Additionally, since there are no currently registered foliar uses for fipronil in the U.S., there are no relevant routes of exposure that would trigger this study. Finally, the above referenced seedling emergence study (Guideline Number 850.4100) clearly concludes that fipronil (an insecticide), which is applied at exceptionally low rates, poses no risk to terrestrial plant species. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 30)

**EPA Response:** The Agency agrees that foliar vegetative vigor studies are not needed for the current suite of fipronil uses.

*EPA Requirement: Hyalella azteca 42-d Test for Measuring the Effects of Sediment associated Contaminants on Survival, Growth, and Reproduction and Life-cycle Test for Measuring the Effects of Sediment-associated Contaminants on Chironomus dilutus (formerly known as C. tentans) both with fipronil*

**Comment:** The Registrants have performed a large amount of higher tiered work to examine potential effects in the environment. In a simulated pond study (MRID 46733901), it was determined that some minor effects may have occurred early in the study for planktonic copepods but that recovery was evident by day 14. In the same pond study, reductions in midges were observed but appeared to recover by day 56. Fipronil and relevant metabolites/degradates were measured in water and sediment during this study.

A field sediment recolonization study was conducted to further investigate potential effects of fipronil to benthic organisms (MRID 47245001). The conclusion from this study is that while fipronil effects are possible for sediments spiked homogeneously with relatively high levels of fipronil, potential impacts are isolated and transient. The method of spiking and deployment are considered very conservative related to likely sediment concentrations resulting from runoff from application of the product. With tens of thousands of individuals observed at 8 geographically distinct sites, only 3 taxa (1 at Lake Tuscaloosa, AL and 2 at Sandhills Research Station Lake, SC) exhibited reductions that may have resulted from fipronil exposure. The potential for impacts on benthic invertebrate communities from currently labeled uses of fipronil is minimal. Overall, in this higher tiered field study, fipronil had minimal impact to benthic invertebrates colonizing the trays. This conclusion supports a finding of low risk to benthic species.

Therefore, the chronic tests with freshwater benthic invertebrates should not be included in a data call-in for fipronil since such data have already been submitted. (BCS, p. 11 and 12)

**Comment (*Hyaella azteca*):** A comprehensive 1-year evaluation (final and interim reports) of the impact of fipronil and its metabolites and degradate on sediment dwelling organisms (multiple taxa) from several sites encompassing ponds, lakes and stream environments has been conducted and was submitted to EPA previously. (MRID No. 47245001: Burton, G.; LaPoint, T.; Kennedy, J.; \*et. al. (2007) *An Assessment of Fipronil Effects on Benthic Invertebrates in Freshwater Ecosystems: Final Report*. Project Number: 2007/7009480, 47152301, 46936104. Unpublished study prepared by BASF Corporation, University of North Texas and Wright State University. 1013p; MRID No. 47152301: Burton, G.; Lapoint, T.; Kennedy, J.; et al. (2007) *An Assessment of Fipronil Effects on Benthic Invertebrates in Freshwater Ecosystems Supplemental Interim Report to MRID No. 46936104*. Project Number: 2007/7006915, 137834, EBFY003. Unpublished study prepared by BASF Corporation, Wright State University and University of North Texas. 875p; and MRID No. 46936104U: Burton, G.; La Point, T.; Kennedy, J. (2006) *An Assessment of Fipronil Effects on Benthic Invertebrates in Freshwater Ecosystems, An Interim Report*. Project Number: 137834, 2006/7010016. Unpublished study prepared by Wright State University, University of North Texas and Bayer CropScience LP. 45p.)

This EPA-suggested non-guideline study is not as comprehensive and is not necessary given that “real world” data has been collected and already provided to EPA. As such,

BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 30 and 31)

**Comment** (*Chironomus dilutus*): Numerous higher tier, “real world” studies have been conducted to examine potential effects of fipronil in the environment. A simulated pond study (MRID No. 46733901; Hoberg, J. (2005) Chipco Topchoice - Effects on Aquatic Fauna in Outdoor Simulated Ponds. Project Number: 13798/6164, EBFY001, 2005/7004401. Unpublished study prepared by Springborn Smithers Laboratories. 281p), as well as a comprehensive 1-year evaluation (final and interim reports) of the impact of fipronil and its metabolites and degradate on sediment dwelling organisms (multiple taxa) from several sites encompassing ponds, lakes and stream environments has been conducted and was submitted to EPA previously. (MRID No. 47245001: Burton, G.; LaPoint, T.; Kennedy, J.; \*et. al. (2007) *An Assessment of Fipronil Effects on Benthic Invertebrates in Freshwater Ecosystems: Final Report*. Project Number: 2007/7009480, 47152301, 46936104. Unpublished study prepared by BASF Corporation, University of North Texas and Wright State University. 1013p; MRID No. 47152301: Burton, G.; Lapoint, T.; Kennedy, J.; et al. (2007) *An Assessment of Fipronil Effects on Benthic Invertebrates in Freshwater Ecosystems Supplemental Interim Report to MRID No. 46936104*. Project Number: 2007/7006915, 137834, EBFY003. Unpublished study prepared by BASF Corporation, Wright State University and University of North Texas. 875p; and MRID No. 46936104U: Burton, G.; La Point, T.; Kennedy, J. (2006) *An Assessment of Fipronil Effects on Benthic Invertebrates in Freshwater Ecosystems, An Interim Report*. Project Number: 137834, 2006/7010016. Unpublished study prepared by Wright State University, University of North Texas and Bayer CropScience LP. 45p.)

The EPA-suggested non-guideline study is not as comprehensive and is not necessary given that “real world” data has been collected and already provided to EPA. As such, BASF requests that this EPA-anticipated data requirement be waived. (BASF, p. 31 and 32)

**EPA Response:** These sediment toxicity testing requirements are consistent with those being recommended for other pesticides with similar chemical and toxicological properties (e.g., many pyrethroids) and provide EFED risk assessors with an understanding of potential direct effects of compounds on benthic invertebrates using standardized test methods. These methods enable quantification of direct effects of chemical exposure on endpoints of concern to the Agency (survival, growth, development and reproduction) using a statistically robust experimental design. Depending on the outcome of these lower tier laboratory studies, additional higher tier studies may be required that would better enable to understand effects (both direct and indirect) under the most vulnerable conditions when chemicals are used according to the label. While EFED acknowledges the registrant's field study submission and will consider these in its forthcoming ecological risk assessment, there is uncertainty whether these studies adequately addressed direct effects that would only become apparent through completion of these lower tier studies. Additionally, incident data are available for compounds which underscore the need for a more comprehensive understanding of

direct effects. There is also uncertainty regarding how representative the field studies are of vulnerable test conditions/species assemblages.

### *Editorial Issues*

#### *Specific Comments on EPA-HQ-OPP-2011-0448-0006: Fipronil Problem Formulation Document (BCS, p. 16 and 20):*

##### Page 7

**EPA Comment:** “Ground water concentrations for fipronil..... The proposed use on in-furrow corn and rutabages/turnip.....”

**BCS Response:** The ground water exposure concentrations may need to be recalculated based on current existing uses.

**EPA Response:** The Agency will recalculate ground water estimated environmental concentrations (EECs) for the current uses and adjust the language accordingly in the risk assessment.

##### Page 8

**EPA Comment:** “Current labels allow outdoor use of fipronil on forestry uses (forest tree management/forest pest management, forest trees (softwoods, conifers), and pine (forest/shelterbelt))”

**BCS Response:** There are no uses for forestry on any Bayer Environmental Science labels.

**EPA Response:** The Agency will adjust the language accordingly.

##### Page 9

**EPA Comment:** “terrestrial non-food crop uses (Christmas tree plantations,”

**BCS Response:** Christmas tree plantations are not on Bayer Environmental Science labels.

**EPA Response:** The Agency will adjust the language accordingly.

##### Page 12

**EPA Comment:** The environmental fate and transport section

**BCS Response:** A higher tier study ((MRID 46936101) was conducted to further understand the environmental fate of fipronil and its metabolites in an outdoor sediment-water system. The analysis shows that the three metabolites degraded significantly faster in the environment than in the laboratory. A description of the study should be included in this section.

**EPA Response:** The Agency will include a description of this study in the risk assessment.

**EPA Comment:** “However, fipronil residue may have the potential to move in very vulnerable soils (e.g., coarse-textured soils with low organic matter content) and in erodible soils when bound to particles entrained in runoff.”

**BCS Response:** High tier column leaching studies have shown the immobility of fipronil, as stated in the EFED document page 16, “Soil column leaching studies confirm the immobility of fipronil”. Therefore, this comment should be removed.

**EPA Response:** The soil column leaching study for the technical grade active ingredient (MRID 42918664) shows higher mobility in coarse textured (sandy) and low organic matter soils. Additionally, recently submitted (since the problem formulation document was completed) study submitted by the registrant (MRID 48287801) also indicates higher mobility of the Termidor® formulation in coarse textured (sandy) and low organic matter soils. The risk assessment text will be updated to include this recently-submitted study.

Page 17

**EPA Comment:** EPA includes a discussion of data collected on the rice use pattern in the aquatic field dissipation section

**BCS Response:** It should be noted in this section that the aquatic field dissipation studies were conducted to support the fipronil rice use, which is no longer registered in the US.

**EPA Response:** The relevant data that has been submitted to the Agency is still used by the Agency even if the use for which the study was submitted has been cancelled.

Page 20

**EPA Comment:** “Only the parent has been tested for reproduction effects in mammals...”

**BCS Response:** This statement is incorrect. As the metabolites MB46136 and MB45950 are also significant animal metabolites, their potential to affect reproduction and health of the young would have been evaluated in all tests with the fipronil parent molecule.

**EPA Response:** The Agency will adjust the language accordingly.

Page 21

**EPA Comment:** “The degree to which the low number of years of outdoor use contributes to a lack of incidents is unknown.”

**BCS Response:** Fipronil has been registered for outdoor use for 15 years. This is sufficient time for ecological incidents to manifest from fipronil use.

**EPA Response:** The Agency will adjust the language accordingly.



Pages 24 and 25

**EPA Comment:** Conceptual models for fipronil exposure are incorrectly characterized.

**BCS Response:** Conceptual models need substantial revision as they do not reflect the exposure pathways for fipronil. Routes that may not significantly contribute to risk are spray drift, leaching to groundwater, atmospheric transport, wet/dry deposition from atmospheric transport, ingestion. There may need to be conceptual models by specific use patterns.

**EPA Response:** The Agency will adjust the language accordingly.

Page 27

**EPA Comment:** "From this model, the Agency will use the "Down-the- drain" module, which is designed for releases to domestic wastewater treatment. It is suitable for all the sources of fipronil and its degradates that could potentially be exposed through a "down-the-drain" scenario."

**BCS Response:** The model referred here (EFAST) is not one of the EPA water models used in the agency's standard exposure assessment. Further information should be provided to justify the appropriate use of the model for exposure assessment such as if the model has been reviewed by an SAP, and what are the fipronil uses the model is suitable for? From the information provided in the EFED document, Bayer does not consider EFAST to be an appropriate model for estimating exposures from the Bayer registered fipronil uses.

**EPA Response:** The Agency will consider models appropriate to down the drain scenarios. The commenter has not described the rationale for their opinion on model suitability so consideration of available models will be limited to Agency experience across the OPP Divisions.

Page 28

**EPA Comment:** "Available monitoring data will be used to qualitatively characterize exposure and compare with modeling results.... monitoring conducted by water management agencies..."

**BCS Response:** BCS agrees that the available monitoring data should be considered in characterizing fipronil exposure. In addition to the monitoring studies conducted by water management agencies, the following monitoring studies should also be considered.

- USGS-NAWQA monitoring data. An in-depth analysis of the NAWQA data in terms of fire ant use from 1999 to 2006 was conducted by the registrants MRID 47438301
- MRID 46733902: Fipronil Water Monitoring Study following Application of Chipco TopChoice to a Golf Course Turf at College Station, Texas
- MRID 46733903: Fipronil Estuarine Monitoring Study Following an Application of Chipco TopChoice to a Gold Course at Gulf Breeze, Florida

- MRID 46733904: Chipco TopChoice Granular Insecticide: Fipronil Natural Runoff and Surface Water in Mecklenburg County, NC
- MRID 46733905: Fipronil Water Monitoring Study Following Application of Chipco TopChoice to a Golf Course Turf at Pickens, Arkansas

Furthermore, higher tier exposure assessments based on the data derived from monitoring studies should also be considered.

- MRID 46936102: Modeling Fate and Transport of Fipronil Following Application of Granular Formulations to Turf: Calibration of Small-Scale Runoff Studies
- MRID 46936103: Modeling Fate and Transport of Fipronil and its Metabolites in Surface Water Following Application of Chipco TopChoice to Turf

**EPA Response:** The Agency will consider all of the relevant submitted data.

#### Page 28

**EPA Comment:** “Two spray drift models, AGDISP and AgDRIFT will be used to assess exposures of terrestrial plants to fipronil deposited in terrestrial habitats by spray drift. AGDRIFT will be used to simulate ground applications”

**BCS Response:** The currently registered use patterns do not allow fipronil spray either by ground or by aerial applications. Therefore, using drift models to assess exposures of terrestrial plants is not appropriate.

**EPA Response:** The Agency agrees and will adjust the language in the risk assessment accordingly.

#### Page 32

**EPA Comment:** Table 4.162-2 (835.4200) anaerobic soil metabolism study “In absence of acceptable data, 2× the aerobic soil metabolism rate will be used in exposure assessment.”

**BCS Response:** This is not a correct statement. Anaerobic soil degradation rate is not required by exposure modeling. So conducting this study will not be of use for exposure and risk assessment.

**EPA Response:** The Agency agrees and will adjust the language in the risk assessment accordingly.

#### Appendix 3

**EPA Comment:** No mention is made of the mysid chronic study submitted in 2005.

**BCS Response:** A higher-tiered mysid study was conducted and submitted to EPA in August 9, 2005 (MRID# 46619103). This study is not described in the problem formulation. A modified mysid life-cycle higher tiered study was designed and using an exposure scenario that would more closely represent realistic chronic exposure. As fipronil is expected to readily partition to the sediment, a static water-sediment design was selected. Traditional mysid life-cycle biological parameters of survival, length of

time to first brood, reproduction, growth (length and weight), and behavior were measured. To evaluate potential differences in toxicity based on developmental stage of the organism, the test was initiated with both juvenile (<24 hr. old) and sexually mature organisms. To add statistical power to the test, 240 mysids (200 juvenile and 40 sexually mature) were exposed at each test concentration and control. Both juvenile and mature mysids were evaluated for reproductive success. Under this realistic exposure scenario, fipronil was much less toxic to mysids. This study should be accounted for in the problem formulation.

**EPA Response:** The Agency will consider the data in the context of repeat exposures anticipated with new introductions of fipronil and degradates as added into aquatic systems with each runoff exposure event. A static system using a single pesticide introduction to water may or may not represent these exposure conditions.

Page 68

**EPA Comment:** EPA states that no NOEC was achieved in the chronic mysid study (MRID 43681201)

**BCS Response:** In the original report, “Machado, M. (1995) Fipronil--Chronic Toxicity to Mysids (*Mysidopsis bahia*) Under Flow-Through Conditions: Final Report: Lab Project Number: 95-4-5820: 10566.1294.6353.530. Unpublished study prepared by Springborn Labs, Inc. 107 p. “there was disagreement on the establishment of a NOEC. This was resolved by the memo, from Anthony F. Maciorowski, Chief, Ecological Effects Branch dated Aug 2, 1996 where EPA established a NOEC for the study.

**EPA Response:** The Agency will review the files for the Anthony F. Maciorowski memorandum and will make any necessary changes to evaluated data sets.

Page 70

**EPA Comment:** EPA states that it only has an interim report from the registrant on the sediment recolonization study.

**BCS Response:** This is incorrect. A full completed report was submitted to EPA in September 2007 (MRID 47245001).

**EPA Response:** The risk assessment will reflect this advancement to a final report.

Page 70

**EPA Comment:** EPA refers to the document as a risk assessment.

**BCS Response:** This document is a problem formulation, not a risk assessment. It only summarizes data from past risk assessments.

**EPA Response:** Noted.

*Specific Comments on Fipronil Summary Document Registration Review: Initial Docket, June 2011 [Docket ID: EPA-HQ-OPP-2011-0448-0003] (BASF, p. 5 and 6)*

**EPA Statement:** Page 4, paragraph 3, last sentence: “Fipronil degrades to form persistent and immobile degradates—fipronil sulfide (MB45950), fipronil sulfone (MB46136), and MB46513.”

**BASF Response:** Fipronil sulfide (MB45950) and fipronil sulfone (MB46136) are animal metabolites, while MB46513 is a photolysis degradate.

**EPA Response:** The Agency has documented that all three degradates are produced in multiple fate studies in Appendix Table 2B of the problem formulation (begins on page 53).

**EPA Statement:** Page 4, paragraph 4, last sentence [and all other Docket occurrences]: “Fipronil was first registered in 1985...”

**BASF Response:** While there were Experimental Use Permits (EUPs) for fipronil in the mid-to-late 1980s, EPA did not grant the first registrations until May 1996 (technical and end-use products).

**EPA Response:** Noted.

**EPA Statement:** Page 10-11, Request for Additional Information:

**BASF Response:** BASF is reviewing and compiling information related to our registered products. This will be provided to EPA in a separate submission.

**EPA Response:** The Agency looks forward to reviewing this information.

**EPA Statement:** Page 12, Use & Usage Information, last bullet [and all other Docket occurrences]: “Application equipment includes low pressure...airplane, and helicopter.”

**BASF Response:** No currently registered fipronil products permit aerial foliar spray application by airplane or helicopter for foliar use on crops.

**EPA Response:** Noted.

**EPA Statement:** Page 13, Ecological Risk Assessment Status, second bullet:

**BASF Response:** Many of the “risk concerns” relate to a specific product or use pattern. Therefore, it is inaccurate to infer (as the bullets do) that these “risk concerns” pertain to the molecule as a whole or to all uses. As with any pesticide, certain products or use patterns have more “risk concern” than others. As such, EPA should specify which “risk concern(s)” go with which products and use patterns. Only then can registrants and the public understand the reasoning behind potential data requirements.

**EPA Response:** The Agency will consider all taxonomic risk groups in the conduct of the risk assessment for fipronil. If there are uses that constitute incomplete exposure pathways for one or more taxa, there may be no quantitative assessment of risks for that use and taxa combination.

**EPA Statement:** Page 16-17, Incidents:

**BASF Response:** EPA indicated that between 2000 and 2010 4,243 incidents involving fipronil were reported. As EPA states in the Fipronil: Review of Human Incidents dated March 1, 2011 [Docket ID: EPA-HQ-OPP-2011-0448-0005] "Reports of adverse health effects allegedly due to a specific pesticide exposure (i.e., an "incident") are largely self-reported and therefore, generally speaking, neither exposure to a pesticide or reported symptom (or the connection between the two) is validated. Typically, causation cannot be determined based on incident data." And while BASF agrees with EPA that incident information can be an important feedback loop, it is equally important for EPA to acknowledge that reported incidents are just that, reported incidents and not confirmed. Additionally, in all likelihood, many incidents probably occurred from off-label use and/or misuse of the product, not due to the toxicity of fipronil to humans, animals or the environment.

While usage data is typically proprietary, in a press release in 2009, a company stated in response to an EPA advisory for products containing fipronil that are used as pet spot-on treatments that since 1996, when the product was first registered, over 1 billion doses have been sold. That is approximately 80 million per year for this one use site.

**EPA Response:** Noted.

*Specific Comments on Registration Review – Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered Species, and Drinking Water Assessments for Fipronil (PC Code 129121; DP 387319) (dated May 4, 2011) [Docket ID: EPA-HQ-OPP-2011-0448-0006] (BASF, p. 7 through 11)*

**EPA Statement:** Page 5, paragraph 1: "Current outdoor uses include...in-furrow treatment for control of corn root worm on corn..."

**BASF Response:** There are no currently registered products that permit in-furrow treatment for control of corn root worm on corn. Likewise for bait treatments for Texas leaf-cutter ants.

**EPA Response:** The risk assessment will incorporate any changes in labeled use.

**EPA Statement:** Page 6, Conclusions from Previous Risk Assessments: "Fipronil was first registered in 1993."

**BASF Response:** While there were EUPs for fipronil in the mid-to-late 1980s, EPA did not grant the first registrations for fipronil until May 1996 (technical and end-use products).

**EPA Response:** Noted.

**EPA Statement:** Pages 7-8, Drinking Water Exposure Assessments: “From the registered and proposed uses for fipronil, the highest concentration... The proposed use on in-furrow corn and rutabagas....”

**BASF Response:** There are no pending proposed or current fipronil registrations that permit application to onion seed or in-furrow corn treatments. The registration for rutabaga/turnip use is a Section 18 Emergency Exemption requested by the state of Oregon, and subsequently granted by EPA under FIFRA, to control cabbage maggot. Only currently approved uses should be taken into account when calculating the ground water exposure concentrations.

**EPA Response:** The risk assessment will incorporate any changes to the labeled uses.

**EPA Statement:** Page 8, Stressor Source and Distribution, paragraph 1 [as well as occurrences on page 10 in Figure 1 and page 11], “The current and proposed new uses...” and “The use pattern includes...”

**BASF Response:** Soil injection for termite control is missing. Also, there is no direct foliar corn use, only treated corn seed that is exported from the U.S. Therefore, direct application to corn should not be considered in any risk assessment.

**EPA Response:** The risk assessment will incorporate any changes to the labeled uses.

**EPA Statement:** Page 10: “Proposed uses of fipronil on sweet potato...”

**BASF Response:** There is no proposed or currently approved use on sweet potato.

**EPA Response:** The risk assessment will incorporate any changes to the labeled uses.

**EPA Statement:** Page 11, paragraph 1: “The proposed pine seedling use...” and “The proposed perimeter house treatment...”

**BASF Response:** This pine seedling use was approved and is on the label of a currently registered end-use product. Likewise, perimeter house treatments using fipronil were approved.

**EPA Response:** The risk assessment will incorporate any changes to the labeled uses.

**EPA Statement:** Page 11, paragraph 2: “The screening level use assessment...”

**BASF Response:** There are no currently registered products that permit in-furrow treatment of corn, only seed treatment of corn that is exported from the U.S. Based on

BASF-known amounts of fipronil used to manufacture formulations for seed treatment of corn that is exported, the screening-level assessment data is incorrect.

**EPA Response:** The risk assessment will incorporate any changes to the labeled uses.

**EPA Statement:** Page 12, Environmental Fate and Transport

**BASF Response:**

- For paragraph 1, the Problem Formulation needs corrected to read, “Fipronil degrades to form the...metabolites fipronil sulfide (MB45950) and fipronil sulfone (MB46136) and the photolytic degradate MB46513.
- As stated by EPA on page 16 of the Problem Formulation, a previously submitted soil column leaching study (a higher tier study) confirmed the immobility of fipronil. As such, EPA should remove the statement “However, fipronil residue may...” from the Problem Formulation.
- A higher tier study was conducted to characterize the degradation of fipronil in an outdoor sediment-water system using kinetics models, and to estimate simple first-order degradation rates of fipronil and its metabolites fipronil sulfide (MB45950) and fipronil sulfone (MB46136) and the photolytic degradate MB46513. Concentrations of all four in water and sediment were measured over time in a simulated pond study and were used to derive parameters describing the fate of the compounds in sediment-water systems under outdoor conditions. Based on the fipronil degradation pathway in the environment and the results of the simulated pond study, simple first-order kinetic models were developed to describe the degradation of fipronil and its metabolites in the sediment-water system. The kinetic models, and thus the study, show that the two metabolites and the photolytic degradate degraded significantly faster in the environment than in the laboratory. (MRID No. 46936101: Tang, Z.; Ramanarayanan, T. (2006) *Degradation of Fipronil and Its Major Metabolites Following Application of Chipco TopChoice Leachate to Outdoor Simulated Ponds: Kinetics Modeling*. Project Number: MEFLX003/1, 2006/7010025. Unpublished study prepared by Bayer Corp. 25p.)

**EPA Response:** The Agency will consider the data referenced in exposure modeling efforts.

**EPA Statement:** Page 13, Table 2:

**BASF Response:** EPA needs to include the “real world” data from MRID No. 47245001 in Table 2. (Burton, G.; LaPoint, T.; Kennedy, J.; \*et. al. (2007) An Assessment of Fipronil Effects on Benthic Invertebrates in Freshwater Ecosystems: Final Report. Project Number: 2007/7009480, 47152301, 46936104. Unpublished study prepared by BASF Corporation, University of North Texas and Wright State University. 1013p.)

**EPA Response:** The Agency will consider these data. However the review of the interim report found in previous risk assessments, unless the final report indicates a significant change in measurements and study conditions, is not likely to change.

**EPA Statement:** Page 17, Aquatic Field Dissipation:

**BASF Response:** The stated information includes data related to use on rice. There is no direct application to rice registered in the U.S. As such, EPA needs to acknowledge that these uses are no longer relevant.

**EPA Response:** Direct applications to rice will not be assessed in the risk assessment. Effects data from rice applications are pertinent to the risk assessment however as they provide information on environmental fate and field related effects. The Agency will however consider the magnitude of exposure the aquatic systems were likely subjected to before extrapolating to all aquatic systems receiving fipronil and degradates from other uses.

**EPA Statement:** Page 20, Effects on Terrestrial Organisms, paragraph 2, last sentence, “Only the parent has been tested for reproductive effects in mammals...”

**BASF Response:** This statement is incorrect. Both animal metabolites MB45950 and MB46136 would have been evaluated in all animal studies (including reproductive studies) in which fipronil was tested as they are both significant animal metabolites.

**EPA Response:** The agency will seek methods to incorporate metabolite identification in establishing effects thresholds for compounds not directly tested without parent or other metabolites.

**EPA Statement:** Page 21, Ecological Incidents, paragraph 1, last sentence, “The degree to which the low number of years of outdoor use...”

**BASF Response:** Fipronil has been registered in the U.S. since 1996 with EUP trials dating further back. Thus, at a minimum, there is 15 years worth of data, which is not a low number of years.

**EPA Response:** The Agency agrees that 15 years is a long time and will adjust the language accordingly. However, given that the incidents expected from application of an insecticide would typically be insect kills in non-target areas (such as aquatic macroinvertebrate die-offs), it is doubtful that such incidents would be noticed or reported. Therefore, the absence of reported incidents should not be considered as evidence of the absence of incidents.

**EPA Statement:** Page 23, Risk Hypothesis, 2nd paragraph, “Application to foliar surfaces may serve...”



**BASF Response:** There are no products registered in the U.S. that permit foliar application of fipronil.

**EPA Response:** The risk assessment will incorporate any changes to the labeled uses.

**EPA Statement:** Pages 23-25, Conceptual Diagram:

**BASF Response:** The conceptual models need substantial revision as they do not reflect the exposure pathways for fipronil. Routes that may not significantly contribute to risk are spray drift, leaching to groundwater, atmospheric transport, wet/dry deposition from atmospheric transport, ingestion. There may need to be conceptual models by specific use patterns.

**EPA Response:** Several commenters noted problems with our depicted conceptual models. These will be altered to more accurately reflect the Agency's conceptual model for the fipronil risk assessment.

**EPA Statement:** Page 27, paragraph 3:

**BASF Response:** EFAST, the model referenced by EPA, is not one of EPA's standard water models used for exposure assessment. As such, EPA needs to provide further information to justify the appropriate use of the model for exposure assessment (e.g. has the model been reviewed by SAP, for what fipronil uses is the model suitable).

**EPA Response:** Details on the E-FAST model can be found at <http://www.epa.gov/oppt/exposure/pubs/efast.htm>.

**EPA Statement:** Page 28, paragraph 2: "Available monitoring data will be used to qualitatively characterize exposure and compare with modeling results ... monitoring conducted by water management agencies..."

**BASF Response:** BASF agrees that available monitoring data should be considered in characterizing fipronil exposure. The following monitoring studies already been submitted by registrants, MRID Nos. 4743830, 46733902, 46733903, 46733904, 46733905)

**EPA Response:** These registrant submitted studies will be considered in the risk assessment.

**EPA Statement:** Page 28, paragraph 3: "Two spray drift models...will be used to assess exposure..."

**BASF Response:** There are no registered foliar applications of fipronil; therefore, using these models does not make sense.

**EPA Response:** The Agency will incorporate all label changes into an updated use evaluation for risk assessment.

**EPA Statement:** Page 29, Integration of Exposure and Effects:

**BASF Response:** There are no registered terrestrial non-food crop field corn uses.

**EPA Response:** The Agency will incorporate all label changes into an updated use evaluation for risk assessment.

**EPA Statement:** Page 32, Table 4, 158 Guideline 162-2:

**BASF Response:** EPA's note in the comment column is not a correct statement. Anaerobic soil degradation rates are not required for exposure modeling, thus conducting a study will not provide relevant data for exposure and risk assessment purposes.

**EPA Response:** The note is incorrect and should not have been included in this table.

**EPA Statement:** Pages 43-50, Appendix 1 of the Problem Formulation, Currently Registered Uses for Fipronil:

**BASF Comment:** Page 47 lists corn, field as terrestrial non-food + residential. This is incorrect. As a seed treatment, it should be terrestrial food + feed crop.

**EPA Response:** Noted, but not relevant to assessment of risk.

**EPA Statement:** Appendix 3 of the Problem Formulation. Available effects data from most recent ecological risk assessment in 2007:

**BASF Response:** Appendix 3 does not make reference to or include any of the data from MRID No. 46619103 (Fipronil - Life-Cycle Toxicity Test with Mysids (*Americamysis bahia*) Under Static Conditions in a Water Sediment System. Project Number: 986/6163, 198247, 2005/5000047. Unpublished study prepared by Springborn Smithers Laboratories. 68p), a higher tier study ran under more environmentally realistic conditions. The resulting NOEC is twelve times higher than that generated in MRID No. 43681201 (Machado, M. (1995) Fipronil--Chronic Toxicity to Mysids (*Mysidopsis bahia*) Under Flow-Through Conditions: Final Report: Lab Project Number: 95-4-5820: 10566.1294.6353.530. Unpublished study prepared by Springborn Labs, Inc. 107p.)

**EPA Response:** The Agency will consider the data in the context of repeat exposures anticipated with new introductions of fipronil and degradates as added into aquatic systems with each runoff exposure event. A static system using a single pesticide introduction to water may or may not represent these exposure conditions.

**BASF Response:** On page 68, EPA states that no NOEC was achieved in the chronic mysid toxicity study. This is incorrect. After an extensive review of this study, as stated in several EPA Memoranda, it was determined that a NOEC of 0.005 ug/L was reached.

**EPA Response:** The Agency will investigate the referenced letter and make any changes appropriately.

**BASF Response:** On page 70, in the 2nd paragraph, EPA states that only an interim report has been submitted for the sediment recolonization study. This is incorrect. The final report for the sediment recolonization study was submitted to EPA on October 2, 2007 as MRID No. 47245001. (*Burton, G.; LaPoint, T.; Kennedy, J.; \*et. al. (2007) An Assessment of Fipronil Effects on Benthic Invertebrates in Freshwater Ecosystems: Final Report. Project Number: 2007/7009480, 47152301, 46936104. Unpublished study prepared by BASF Corporation, University of North Texas and Wright State University. 1013p.*) Also, in the last sentence EPA refers to "...the drafting of this risk assessment." This is a typo and should be Problem Formulation.

**EPA Response:** The Agency will consider these data. However the review of the interim report found in previous risk assessments, unless the final report indicates a significant change in measurements and study conditions, is not likely to change.